

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

RETRACTABLE TECHNOLOGIES, INC.	§	
AND THOMAS J. SHAW,	§	
Plaintiffs,	§	CIVIL ACTION NO. 2:08-cv-16
	§	(FOLSOM)
v.	§	
	§	
BECTON, DICKINSON AND COMPANY,	§	
	§	
Defendant.	§	<hr style="width: 30%; margin: 0 auto;"/> JURY TRIAL DEMANDED
	§	

**SECOND AMENDED COMPLAINT**

Retractable Technologies, Inc. (“Retractable”) and Thomas J. Shaw (collectively “Plaintiffs”) complain of Defendant Becton, Dickinson and Company (“BD”) and for cause would show as follows:

**INTRODUCTION**

BD has had a monopoly in the hypodermic syringe market for over fifty years stretching back to when syringes were made of glass, sterilized after each use and then reused. Since the mid-1960’s disposable plastic syringes have replaced the original glass syringes, adding the advantage of disposability but creating the problem of contamination because plastic, unlike glass, cannot be easily sterilized for reuse. Since the late 1980’s medical professionals have known that accidental needlesticks of healthcare workers from hypodermic syringes, where the tip of a contaminated needle accidentally pierces the skin, can and do transmit deadly blood-borne diseases such as hepatitis and HIV. In addition, even when a clean needle is used, the reuse of plastic syringe bodies contaminated with a first person’s body fluids but then used to give a second injection to a second person can and does transmit diseases from the first to the second

person. For over twenty years BD has known that its plastic hypodermic syringe products cause accidental injury and deaths due to syringe reuse and accidental needlesticks. With its long-held monopoly in conventional plastic syringes, BD was in both a precarious and awkward position as the evidence mounted that its base product line was dangerous to both patients and healthcare workers. Any products recognized to effectively stop accidental needlesticks and prevent syringe reuse would, in an open and free market, pose a real challenge to the monopoly market position BD has enjoyed for decades through sales of its dangerous conventional hypodermic syringes.

Plaintiffs' patented retractable needle syringe products effectively eliminate accidental needlesticks and syringe reuse. When using Plaintiffs' retractable syringe products, the sharp needle automatically retracts out of the body and up into the syringe barrel, preventing accidental needlesticks. Upon triggering of the retraction, the plunger seal of the syringe is dislodged so that the syringe cannot be used for a second injection of fluid. The automatic retraction feature protects the nurse delivering the medication from an accidental needlestick and the disruption of the plunger seal insures that the syringe cannot be reused on a second patient. The combination of the two features provides total safety for both healthcare worker and patient.

BD fully understands that only automatic retracting needle technology such as that found in Plaintiffs' patented products provides total safety by eliminating accidental needlesticks for healthcare workers while stopping syringe reuse to protect patients. BD has recognized that eventually the entire health community will demand this type of total safety. But BD has no products that fall outside Plaintiffs' patent protection that can meet that coming worldwide market demand. BD also has a vested interest in keeping all hypodermic syringe products tied to use of its molds and tooling for conventional syringes instead of allowing the market to adopt

newer and safer advanced technology. It is BD's actions in attempting to maintain its monopoly position by containing, controlling, excluding, or eliminating Plaintiffs' new and advanced safety syringe technology and related products that form the basis of this action.

Thus, Plaintiffs' bring this action to open the market so that healthcare workers and patients can freely access lifesaving safety syringe and needle products based on innovation, quality and price and to recover for damages caused by BD's tortious and anti-competitive conduct. BD has used its monopoly position to unlawfully stifle competition and the syringe consuming public's enjoyment of innovative products that can guard against the continuing problem of accidental needlestick injuries and syringe reuse. Rather than allow competition to be on the basis of the safest products for the best price, BD has harmed Plaintiffs and the public through behavior that includes patent infringement, false advertising, unfair competition, and exclusionary conduct. These acts and others are intended to and have maintained BD's monopoly power in the hypodermic syringe market and have allowed BD to leverage that monopoly to obtain market power in the market for safety syringe products in acute care facilities. BD has further used its monopoly power in the developing safety syringe market to exclude Plaintiffs' retractable syringes from the acute care market.

For the sake of maintaining its market share and to keep Plaintiffs' life-saving safety syringe technology from becoming the new accepted standard for syringe safety, BD continues to sell so called "safety" syringe products it knows to be clinically sub-optimal war brands whose purported safety features are known to be ineffective in reducing needlestick injuries. Its products, that include some variety of a shield that must be positioned over the dangerous needle by the healthcare worker, do not guard against reuse of the syringe itself. Thus, even if the shield mechanism operates to cover the needle, the syringe portion of the device can be reused

with a second needle, allowing for spread of disease. BD has harmed Retractable and the American public, and is continuing to harm Retractable and the American public, by falsely advertising BD's inferior, shielded syringe products as "safe," "safety," or "safety engineered." BD employs these illegal acts to leverage its monopoly in conventional hypodermic products and obtain or maintain a monopoly in the safety syringe market created by passage of the Needlestick Safety and Prevention Act of 2000 that requires health care organizations to procure "safety" products to protect their workers.

Recognizing that safety syringes with an automatic retraction feature that could not be reused would attract market attention, BD designed and marketed its own brand of retractable syringes called the Integra. The BD Integra syringes were rushed to market in 2002 to 2004 in an effort to stop Plaintiffs' VanishPoint<sup>®</sup> retracting syringes from gaining any appreciable market share. In the rush to stave off even the possibility of loss of market share, BD took the Integra retractable syringes to market knowing they had serious performance issues as a result of poor design that caused unnecessary risks and failures in the hands of healthcare workers. BD well knew of the deficiencies of its retractable syringe products, but covered up design performance issues so as to obtain FDA clearance and pretend to meet demands from customers who wanted the total safety of a retractable syringe product. BD used the Integra syringes, which infringed upon Plaintiffs' patents, to block Plaintiffs' life-saving products from the acute care market. The poor quality and performance of the Integra has damaged consumer opinions on retractable syringe technology in general, harming both Plaintiffs and the public while boosting sales of BD's inferior and dangerous shielded syringe products sold as being "safe."

In addition to marketing shielded needle products which did not provide any real safety and tainting the market for retractable syringes with inferior if not dangerous products, BD has also harmed Plaintiffs through unfair competition in the marketplace, including product disparagement, false advertising regarding Plaintiffs VanishPoint<sup>®</sup> syringe products and interference with prospective relations designed to increase Plaintiffs' costs and deny Plaintiff the efficiencies of volume production.

Finally, BD has harmed Retractable and the American public, and is continuing to maintain its monopoly power and harm Retractable and the American public by employing unlawful exclusionary contracting schemes, including bundling, loyalty discounts, rebates and tying arrangements that require customers to buy a host of BD products or to buy from BD for substantially longer than one year in order to obtain the most favorable pricing on its safety syringe products. BD's control of the hospital market for safety syringes allows it to tie sales of retractable syringes to the market for less safe devices that purport to offer safety but do not. This conduct not only freezes out Retractable's superior safer technology, it directly harms the public by frustrating the legislative intent of the Needlestick Safety and Prevention Act that requires yearly reviews and adoption of the safest syringe technology available.

### **NATURE OF THIS ACTION**

1. Plaintiffs' patented safety syringe technology virtually eliminates the risk of needlestick injuries to healthcare workers. Needlestick injuries can transmit to healthcare workers potentially deadly diseases such as hepatitis B, hepatitis C, and Human Immunodeficiency Virus ("HIV"), the virus that causes AIDS. The American Nurses Association estimates that more than 600,000 contaminated needlestick injuries are reported each year in the United States. (See [www.nursingworld.org/readroom/fsneedle.htm](http://www.nursingworld.org/readroom/fsneedle.htm).)

2. Clinically-based market surveys in the early 2000's found that automatic retractable syringe technology such as that owned and sold by Plaintiffs literally wowed survey participants and was projected to capture upwards of 70% of the then nascent market for safety syringe products. Plaintiffs' syringe products also protect patients because they cannot be reused on a second patient. Yet today only about 5% of safety syringe products have the automatic retractable type of operation and many nurses and healthcare workers are still unaware that such life-saving technology even exists.

3. More disturbingly, while some uses of needles have been replaced by needleless systems almost ten years after the passage of the Needlestick Safety and Prevention Act, there is no reliable evidence that the number of needlestick accidents per syringe actually used has dropped and much evidence that the accident rate has either increased or remained the same despite the sale of billions of higher cost (and higher profit) so-called "safety syringe" products by BD.

4. BD is the nation's dominant maker and seller of disposable syringes and other needle products. BD is using a combination of intentional, unlawful conduct, including patent infringement, false advertising, unfair competition, and exclusionary monopolistic behavior, to suppress competition, innovation, and Retractable's access to and success in the market. BD intends to delay widespread adoption of automatic retractable syringe technology and hold Retractable's technology off the market until Plaintiffs' patents expire and BD can decide whether using that superior technology for free or continuing to extract maximum profits from BD's existing, but obsolete and dangerous, needle-product technologies best suits its desire to maintain its monopoly. By its unlawful conduct, BD has denied, and continues to deny,

American healthcare workers access to Retractable's products, which are available now, and which incorporate the most innovative and effective safety technology available.

5. Plaintiffs file this action seeking judicial relief to terminate BD's unlawful conduct. If unchecked, BD will continue to deceive the market through false advertising about its own and others' products and other unfair competition and unlawful, monopolistic, exclusionary conduct. BD's conduct is greatly and irreparably damaging Plaintiffs, denying American healthcare workers and patients the immediate benefits of Retractable's superior safety needle products, and unfairly tending to destroy competition itself in the relevant markets.

6. For all its claims herein, Plaintiffs seek injunctive relief and damages accruing after July 2, 2004.

### **PARTIES**

7. Plaintiff Retractable is a Texas corporation with its principal place of business in Little Elm, Texas, within the Eastern District of Texas. Retractable is a publicly-traded company that employs approximately 150 persons within this District.

8. Plaintiff Thomas J. Shaw is an individual residing in Frisco, Texas.

9. Defendant BD is a New Jersey corporation with its principal place of business in Franklin Lakes, New Jersey. BD has already been served with process in this action and has appeared through its counsel of record.

### **JURISDICTION AND VENUE**

10. This Court obtained subject matter jurisdiction under the patent laws set forth in Title 35 of the United States Code and in Title 28 of the United States Code, particularly 28 U.S.C. §§ 1331 and 1338(a) from the original complaint filed in this action from which the causes herein were severed by this Court's order; Section 43(a) of the Lanham Act, 15 U.S.C. §

1125(a)(1)(B); the Sherman Act, 15 U.S.C. §§ 1 *et seq.*; Sections 3, 4 and 16 of the Clayton Act, 15 U.S.C. §§ 14, 15 and 26; and 28 U.S.C. §§ 1331 and 1337. This Court has supplemental jurisdiction over Retractable's state law claims pursuant to 28 U.S.C. § 1367 because they are so related to and intertwined with Retractable's federal claims as to form a part of the same case or controversy. In addition, this Court has jurisdiction under 28 U.S.C. § 1332(a) because this action is between citizens of different states and the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

11. This Court has personal jurisdiction over BD because of BD's numerous and extensive contacts with the Eastern District of Texas. BD holds a certificate of authority to transact business in Texas and regularly transacts business within Texas and the Eastern District of Texas.

12. BD has and does market its infringing "Integra" 1 cc and 3 cc syringes within Texas and the Eastern District of Texas.

13. BD's commercial activities carried on in Texas and elsewhere throughout the United States have had a substantial, direct and reasonably foreseeable effect on business and commerce in the Eastern District of Texas and on interstate commerce.

14. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c), 28 U.S.C. § 1400(b), and 15 U.S.C. § 22.

### **BACKGROUND FACTS**

15. BD was founded in 1897; its first product was an all-glass syringe. By the 1950s, BD had become the leading U.S. hypodermic syringe manufacturer. Its product line also included blood collection products and IV catheters.

16. In 1964, BD entered into a consent judgment with the United States Department of Justice that prohibited BD's continuation of monopolistic practices in the glass syringe market. That judgment, which is technically still in force, specifically related to only *glass syringes* even though BD was in the process of shifting its entire manufacturing and illegal marketing practices to *plastic* disposable syringes. Its "Plastipak" plastic disposable syringe was introduced in the 1960's and allowed BD to continue its monopolistic practices with impunity.

17. For decades now, BD has maintained dominance in the market for disposable syringes (conventional and safety), which replaced glass syringes. In 2005 BD was estimated to control over 70% of the United States market for syringes and needles. ("U.S. Syringes and Needle Markets", F876-54, 2-29, Frost & Sullivan, 2006.)

18. Even as the market for safety needle and IV catheter products has grown, conventional needle products still possess a significant share of the overall market. A recent study projected there will still be a 50-50 split of the market as late as 2012. ("U.S. Syringes and Needle Markets", F876-54, 1-5, Frost & Sullivan, 2006.) As a result, BD has a strong economic incentive to keep Retractable out of the market for safety needle products, not only so BD can maintain its prices for those products, but also so it can maintain its monopoly in non-safety product lines.

19. Almost all needle products sold today are marketed in both alleged "safety" and non-safety forms. Although safety and non-safety products perform the same function, safety products should reduce the risk of needlestick injury. The Needlestick Safety and Prevention Act has mandated use of "safer" products. BD and other manufacturers are able to charge, and healthcare workers are willing to pay, a higher price for Needle Products marketed as "safe,"

“safety,” or “safety-engineered” products. As a consequence, safety and non-safety versions of these products are today in separate product sub-markets and have been since at least early 2004.

20. The relevant product markets impacted by BD’s antitrust violations are the nationwide markets for the manufacture and distribution of hypodermic syringes (both conventional and safety), safety needle devices (the portion of the hypodermic syringe market that is purported to provide safety over conventional products), IV catheters (safety and conventional) and safety IV catheters (the portion of the IV catheter market that is purported to provide safety over conventional products). Each of these product markets also have relevant markets based on whether the customer is in the acute or alternate care submarkets for healthcare products. A monopolist in these markets such as BD is able to maintain the prices of these products above a competitive level without losing customers. BD’s violations of the antitrust laws have foreclosed and continue to foreclose Retractable from the market for hypodermic syringes, safety needle devices, IV catheters and IV safety catheters in the total market, the acute care market and the alternate care market.

21. Hypodermic syringe products, both conventional and safety, sold to the total healthcare market in the U.S. constitute a relevant market because there are no substitutes for the use of these products to inject medications into the body. Hypodermic syringe products include syringe bodies of various capacities, for example, 1cc, 3cc, 5cc and 10cc (“cc” and “mL” or “ml” are used interchangeably). Conventional syringe bodies without fixed needles are sold in either a luer slip or a luer-lok configuration. Recently Retractable attempted to introduce into the market the first syringe body that provides added safety for the patient through use of a feature that guards against infection called the Patient Safe™. Manufacturers of other medical products cannot easily switch to manufacturing hypodermic syringes because those products use different

technology, are subject to different patents and require different capital equipment, including both molds and assembly equipment special to the manufacture of hypodermic syringes.

22. Hypodermic syringe products, both conventional and safety, sold to the acute care market also constitute a relevant market because there are no substitutes for the use of these products to inject medications into the body. The acute care market is composed of hospitals and related facilities that perform surgery on an in-patient basis. Hypodermic syringe products include syringe bodies of various capacities, for example, 1cc, 3cc, 5cc and 10cc. Conventional syringe bodies without fixed needles are sold in either a luer slip or a luer-lok configuration. Recently Retractable attempted to introduce into the acute care market the first syringe body that provides added safety for the patient through use of a feature that guards against infection called the Patient Safe™. Manufacturers of other medical products cannot easily switch to manufacturing hypodermic syringes because those products use different technology, are subject to different patents and require different capital equipment, including both molds and assembly equipment special to the manufacture of hypodermic syringes.

23. Hypodermic syringe products, both conventional and safety, sold to the alternate care market constitute another relevant market because there are no substitutes for the use of these products to inject medications into the body in those locations. The alternate care market is composed of alternate care facilities that provide long-term nursing care, out-patient surgery, emergency care, physician services and the like. Just as in acute care, hypodermic syringe products include syringe bodies of various capacities, for example, 1cc, 3cc, 5cc and 10cc. Conventional syringe bodies without fixed needles are sold in either a luer slip or a luer-lok configuration. Recently, Retractable attempted to introduce into the alternate care market the first syringe body that provides added safety for the patient through use of a feature that guards

against infection called the Patient Safe™. Just as in acute care, manufacturers of other medical products cannot easily switch to manufacturing hypodermic syringes for the alternate care market because those products use different technology, are subject to different patents and require different capital equipment, including both molds and assembly equipment special to the manufacture of hypodermic syringes.

24. Safety needle devices sold to the total U.S. healthcare market constitute a distinct product market from conventional needle devices. The relevant market for the manufacture and distribution of safety needle devices is a distinct market because both suppliers and purchasers view safety needle devices as distinct products. Safety needle devices also cost more than conventional needles and syringes. Hospitals and healthcare workers distinguish between alleged safer needle devices and their counterpart devices because of user preference for a safer alternative and to avoid the costs involved in disease or death resulting from needlestick injuries. Federal and state laws and regulations mandating use of safer products also cause hospitals and healthcare workers to distinguish between conventional needle products and safety needle devices. Thus, healthcare workers, the end users do not consider conventional needle products and safety needle devices to be substitutes for each other.

25. Safety needle devices sold to the acute care market constitute a distinct product market from conventional needle devices sold to the same market. The relevant market for the manufacture and distribution of safety needle devices to acute care providers is a distinct market because both suppliers and purchasers view safety needle devices as distinct products. Safety needle devices also cost more than conventional needles and syringes. Hospitals and healthcare workers distinguish between alleged safer needle devices and their counterpart devices because of user preference for a safer alternative and to avoid the costs involved in disease or death

resulting from needlestick injuries. Federal and state laws and regulations mandating use of safer products also cause hospitals and healthcare workers to distinguish between conventional needle products and Safety needle devices. Thus, healthcare workers, the end users do not consider conventional needle products and safety needle devices to be substitutes for each other.

26. Safety needle devices sold to the alternate care market constitute a distinct product market from conventional needle devices. The relevant market for the manufacture and distribution of safety needle devices to alternate care providers is a distinct market because both suppliers and purchasers view safety needle devices as distinct products. Safety needle devices also cost more than conventional needles and syringes. Hospitals and healthcare workers distinguish between alleged safer needle devices and their counterpart devices because of user preference for a safer alternative and to avoid the costs involved in disease or death resulting from needlestick injuries. Federal and state laws and regulations mandating use of safer products also cause hospitals and healthcare workers to distinguish between conventional needle products and safety needle devices. Thus, healthcare workers, the end users do not consider conventional needle products and safety needle devices to be substitutes for each other.

27. Furthermore, manufacturers of conventional needle products cannot easily switch to manufacturing safety needle devices because the two types of products require different patents, technology and capital equipment, including both molds and assembly equipment unique to each device. Safety needle devices are significantly more complex products than conventional needle products, incorporating additional moving parts and distinctive design elements.

28. A third relevant products market is the market for IV catheters used to deliver drugs or fluids to a patient through an IV set. The IV catheters can be conventional or have a safety feature.

29. IV catheters, both conventional and safety, sold to the total healthcare market in the U.S., constitute a relevant market because there are no substitutes for the use of these products to deliver medications and other fluids into the body. IV catheters are usually in the form of a cannula-over-needle device in which a flexible plastic cannula comes mounted on a metal trocar (needle). Once the tip of the needle and the cannula are located in the vein the trocar (needle) is withdrawn and discarded and the cannula advanced inside the vein to the appropriate position and secured. Retractable attempted to introduce into the market an improved VanishPoint<sup>®</sup> retracting safety IV catheter that virtually eliminates the possibility of needlestick from the withdrawn trocar (needle) of the device. Manufacturers of other medical products cannot easily switch to manufacturing IV catheters because those products use different technology, are subject to different patents and require different capital equipment, including both molds and assembly equipment special to the manufacture of IV catheters. The barriers of distinct technology, patent considerations and capital equipment expenditures mean that entering the market for IV catheter products would be difficult.

30. IV catheters, both conventional and safety, sold to the acute care segment of the healthcare market in the U.S. constitute a relevant market because there are no substitutes for the use of these products to deliver medications and other fluids into the body at those customer locations. As noted above, IV catheters are usually in the form of a cannula-over-needle device in which a flexible plastic cannula comes mounted on a metal trocar (needle). Once the tip of the needle and the cannula are located in the vein the trocar (needle) is withdrawn and discarded and the cannula advanced inside the vein to the appropriate position and secured. Retractable attempted to introduce into the acute care market an improved VanishPoint<sup>®</sup> retracting safety IV catheter that virtually eliminates the possibility of needlestick from the withdrawn trocar (needle)

of the device. Manufacturers of other medical products cannot easily switch to manufacturing IV catheters because those products use different technology, are subject to different patents and require different capital equipment, including both molds and assembly equipment special to the manufacture of IV catheters. The barriers of distinct technology, patent considerations and capital equipment expenditures mean that entering the acute care market for IV catheter products would be difficult.

31. IV catheters, both conventional and safety, sold to the alternate care segment of the healthcare market in the U.S., constitute a relevant market because there are no substitutes for the use of these products to deliver medications and other fluids into the body at those customer locations. As noted above, IV catheters are usually in the form of a cannula-over-needle device in which a flexible plastic cannula comes mounted on a metal trocar (needle). Once the tip of the needle and the cannula are located in the vein the trocar (needle) is withdrawn and discarded and the cannula advanced inside the vein to the appropriate position and secured. Retractable attempted to introduce into the alternate care market an improved VanishPoint<sup>®</sup> retracting safety IV catheter that virtually eliminates the possibility of needlestick from the withdrawn trocar (needle) of the device. Manufacturers of other medical products cannot easily switch to manufacturing IV catheters because those products use different technology, are subject to different patents and require different capital equipment, including both molds and assembly equipment special to the manufacture of IV catheters. The barriers of distinct technology, patent considerations and capital equipment expenditures mean that entering the alternate care market for IV catheter products would be difficult.

32. Safety IV catheters, sold to the total healthcare market in the U.S., constitute a relevant market because there are no substitutes for the use of these products to deliver

medications and other fluids into the body. The relevant market for the manufacture and distribution of safety IV catheters to the total U.S. market is a distinct market because both suppliers and purchasers view safety IV catheters as distinct products. Safety IV catheters also cost more than conventional IV catheters. Hospitals and healthcare workers distinguish between alleged safer IV catheters and their counterpart devices because of user preference for a safer alternative and to avoid the costs involved in disease or death resulting from needlestick injuries. Federal and state laws and regulations mandating use of safer products also cause hospitals and healthcare workers to distinguish between conventional IV catheters and safety IV catheters. Thus, healthcare workers, the end users do not consider conventional IV catheters and safety IV catheters to be substitutes for each other.

33. Safety IV catheters, sold to the acute care market in the U.S., constitute a relevant market because there are no substitutes for the use of these products to deliver medications and other fluids into the body in those locations. The relevant market for the manufacture and distribution of safety IV catheters to the acute care market is a distinct market because both suppliers and purchasers view safety IV catheters as distinct products. Safety IV catheters also cost more than conventional IV catheters. Hospitals and healthcare workers distinguish between alleged safer IV catheters and their counterpart devices because of user preference for a safer alternative and to avoid the costs involved in disease or death resulting from needlestick injuries. Federal and state laws and regulations mandating use of safer products also cause hospitals and healthcare workers to distinguish between conventional IV catheters and safety IV catheters. Thus, healthcare workers, the end users in the acute care market do not consider conventional IV catheters and safety IV catheters to be substitutes for each other.

34. Safety IV catheters, sold to the alternate care market in the U.S., constitute a relevant market because there are no substitutes for the use of these products to deliver medications and other fluids into the body in those locations. The relevant market for the manufacture and distribution of safety IV catheters to the alternate care market is a distinct market because both suppliers and purchasers view safety IV catheters as distinct products. Safety IV catheters also cost more than conventional IV catheters. Hospitals and healthcare workers distinguish between alleged safer IV catheters and their counterpart devices because of user preference for a safer alternative and to avoid the costs involved in disease or death resulting from needlestick injuries. Federal and state laws and regulations mandating use of safer products also cause hospitals and healthcare workers to distinguish between conventional IV catheters and safety IV catheters. Thus, healthcare workers, the end users in the alternate care market do not consider conventional IV catheters and safety IV catheters to be substitutes for each other.

35. As noted above, there are at least two distinct customer markets for hypodermic syringes and IV catheters. The acute care market, composed of hospitals and related facilities that perform surgery on an in-patient basis, and alternate care facilities that provide long-term nursing care, out-patient surgery, emergency care, physician services and the like, are recognized sub-markets of the overall healthcare market. Even though the same products may be marketed to both types of facilities, differences in volumes, distribution, pricing, and contracting mean that these are separate sub-markets. BD either controls both of these sub-markets for hypodermic syringe products and IV catheters with its overall monopoly and/or market power or has a significant market share in those markets and is attempting to monopolize those markets through the illegal acts described herein.

36. According to an independent study published in 2006, reflecting data from 2005, BD has maintained monopoly power in the market for all needle products. BD had over 71 percent of the total syringe and needle market in 2005. (“U.S. Syringes and Needle Markets”, F876-54, 2-29, Frost & Sullivan, 2006.) After June of 2004 BD has approximately 60 percent of the safety syringe and needle market. BD’s market shares are greater within the acute care sub-market where they hold approximately 75% of the total hypodermic syringe market.

37. The relevant geographic market for the commerce at issue here is the United States. Both BD and Retractable sell their hypodermic syringes, safety needle devices and IV catheters throughout the United States. The Needlestick Safety and Prevention Act uniquely impacts the demand for Safety needle devices throughout the United States. Patent laws and the regulatory conditions for sales of safety needle devices also vary from country to country, making the United States a distinct geographic market.

#### **Retractable’s Life-Saving Safety Syringe Products and Technology.**

38. Retractable markets patented safety syringes under the name “VanishPoint®.” VanishPoint® syringes are covered by a number of patents, including United States Patent Nos. 5,578,011, 5,632,733, 6,090,077 and 7,351,224 (the ‘011, ‘733, ‘077 and ‘224 Patents). VanishPoint® syringes protect against needlestick injuries. VanishPoint® syringes automatically and permanently retract their needle after an injection is given and before the needle is withdrawn from the patient. Consequently, VanishPoint® syringes require no extra action by a healthcare worker to trigger their safety feature after the needle is withdrawn from a patient. Retractable and its VanishPoint® products have been reported favorably in major news features, including in the *New York Times* and on CBS’ *60 Minutes*.

39. VanishPoint<sup>®</sup> syringes have been widely recognized as superior safety products. For one example, in 1999 and thereafter the Emergency Care Research Institute (“ECRI”), a respected testing and evaluation service, has awarded VanishPoint<sup>®</sup> syringes its highest rating and listed them as preferred devices. (*HEALTH DEVICES*, August 2007, Vol. 36, No. 8, at p. 266.) In 2007 an independent study of retractable syringes conducted by PATH (Program for Appropriate Technology in Health) in South Africa concluded VanishPoint<sup>®</sup> syringes were an effective means for “eliminating needlestick injury and preventing reuse.” (Evaluation of a Retractable Syringe in South Africa, PATH, September 2007, p. 5).

40. In addition, Retractable manufactures a safety IV catheter product that was first sold in April 2006 and an innovative safety syringe body called the Patient Safe<sup>™</sup> that Retractable began marketing in 2008. The VanishPoint<sup>®</sup> safety IV catheter utilizes patented automated retraction technology similar to that of the VanishPoint<sup>®</sup> syringe and blood collection tube holder. It is easy to use and allows for one-handed venipuncture. It contains an integrated safety mechanism that, when activated, quickly retracts the introducer needle, which remains safely retracted inside the housing until disposal, substantially reducing the risk of a needlestick injury. Unlike other IV catheters, VanishPoint<sup>®</sup> IV catheters do not require additional components such as sliding sheaths, metal clips or activation buttons.

41. Patient Safe<sup>™</sup> syringes are uniquely designed to reduce the risk of bloodstream infections resulting from catheter hub contamination. Their unique luer guard reduces the risk of luer tip contact contamination. It also reduces the risk of contamination of intravenous fluid. Patient Safe<sup>™</sup> syringes are compatible with most available hypodermic needles, including those with manually activated safety features, vial access devices, and luer-activated catheter hubs.

### **Retractable's Superior VanishPoint® Products are Blocked from the Market**

42. After years of trial and error research, FDA clearance of his products, and formation and funding of a new company, inventor Thomas J. Shaw attempted to bring his VanishPoint® products to market in 1997. It soon became apparent that BD and powerful Group Purchasing Organizations (GPOs), knowing that state and federal safety needle legislation could soon reduce or even eliminate the market for conventional syringes, were determined to protect BD's market share as well as the lucrative fees collected by GPOs as gatekeepers for virtually all sales made to acute care facilities in the United States. Retractable filed a lawsuit on September 30, 1998, against BD, Tyco International (U.S.), Inc., VHA, Inc., and others alleging an antitrust conspiracy between the defendants whereby they contracted among themselves and many other hospitals, doctors, and healthcare organizations for the purpose of excluding Retractable from selling the safety syringes and maintaining their own market share in violation of the law.

43. After six years of litigation, Retractable settled its lawsuit with all parties and released BD from liability other than patent infringement for acts occurring prior to July 2, 2004. BD paid \$100 million for the release. According to BD records, the lawsuit and settlement had "no impact" on its business plans.

44. After the settlement Retractable expanded its sales force and continued efforts to reduce the cost of its retractable syringes by arranging for off-shore production of its products. As a result of that earlier litigation, Retractable was allowed to be listed for the first time as a possible supplier on some GPO contracts. From 2004 through the present, Retractable has employed a nationwide sales staff to attempt to gain access to hospitals and other acute care facilities who are members of the GPOs and who could therefore theoretically buy VanishPoint® products from Retractable at the GPO pricing. All such sales efforts were rebuffed. As a result

of BD's exclusionary contracts, Retractable sales personnel were continually and regularly told that the hospital or other acute care facility was "under BD contract" or had "standardized" on BD or that the facility was not allowed to see a demonstration of the product. Even though Retractable was supposedly one supplier on a "multi-supplier" GPO contract with the facilities, it had no success in selling its retractable safety syringe through GPO contracts.

45. Furthermore, healthcare facilities are required by the Needlestick Prevention Act to have a yearly review meeting with clinicians participating in the decision as to what the safest technology would be for their facility in the coming year. But from 2004 to the present BD's multi-year rebating, loyalty discounts, bundling arrangements and other loyalty sales incentives and payments which Retractable could not possibly match were keeping the doors of acute care facilities firmly shut and in BD's control. In short, even though the GPOs purportedly stopped the worst of their exclusivity practices that favored large suppliers like BD over small innovative companies by allowing Retractable and other small companies to be listed as a potential source of product, the reality is that the GPOs and BD have continued on with business as usual, masking their exclusive dealing through the use of contracting and reward schemes intended to protect market share by freezing out smaller innovative firms that cannot possibly match such offers.

46. In general, these schemes include separate agreements made between the healthcare facility and BD that provides lower pricing or delivers rebates to the customer beyond the listed GPO pricing schedule. As explained more fully below, this scheme of allowing Retractable and other small companies to enter into contracts with the GPOs but also allows BD to provide bundling, rebate, loyalty discounts and other sales incentives that cannot be matched by small suppliers of innovative technology (who are equally efficient in supply of their

particular products but who are incapable of matching these incentives), is one of several schemes specially intended to exclude rivals by denying them the ability to lower their own costs through volume sales. While the GPO contracts that list alternate suppliers give BD's activities the appearance of competitiveness, the reality is that BD is slowly increasing its stranglehold on the market, waiting for smaller competitors such as Retractable to be run out of business.

47. As a result of the lawsuit that finally settled in July of 2004, Retractable was added to the contract of one of the largest GPOs in the nation. Using funding obtained through its settlement, Retractable attempted to use its new ability to access GPO associated hospitals by offering to member hospitals of that large GPO pricing for its VanishPoint<sup>®</sup> products that was 50% less than regular pricing and only pennies more than the prices for conventional, non-safety syringe products. This low pricing was kept in place for eighteen months, so that healthcare facilities attempting to comply with the Needlestick Safety and Prevention Act's requirement for a yearly review of safety products would have access to the pricing.

48. The results of Retractable's sales program proved that BD's exclusive contracts with hospitals make competition based on price and quality impossible. For non-hospital customers qualified to purchase through the GPO, Retractable's deep discounting resulted in an 800% increase in sales volumes over an eighteen month period in 2005-6. But for hospital customers, offered the same pricing over the same period of time, the BD/GPO scheme of secondary agreement barriers such as bundling, rebating and loyalty discounts kept hospital doors shut to Retractable. Even with Retractable's much-reduced pricing, there was virtually no increase in its sales volume to hospital customers.

49. By 2006 it had become clear that BD had not changed its anti-competitive practices and goals at all and that the purported inroads provided by Retractable's settlement

with the GPOs had simply been replaced with a more dense and obfuscated series of exclusionary conduct.

50. In addition to its exclusionary contracting conduct, BD also raised Retractable's costs for the purpose of driving it from the market through (a) patent infringement, (b) tainting of the market against use of retractable syringe products by selling its Integra syringes with known serious design problems that cause users to dislike and reject retractable syringes, lessening any chance that they will ever try the superior performance of the VanishPoint<sup>®</sup> syringe products, (c) false advertising, and (d) product disparagement.

51. From 2004 to the present, BD has used its infringing Integra retractable syringe products to keep hospital doors shut to Retractable by offering the Integra as a supposedly easy-to-use, feature-driven product promising the customer the same advantages as Retractable's patented technology.

52. Because of the Integra, potential customers have told sales personnel for the VanishPoint<sup>®</sup> that they do not like retracting syringes even though they have never tried a VanishPoint<sup>®</sup>, have never purchased VanishPoint<sup>®</sup> syringes and in at least some cases have previously refused to even allow Retractable to demonstrate its products. Except for short periods of time when other infringing retractable products were marketed, if a customer requested a retractable syringe product, the only available choices were Plaintiffs' VanishPoint<sup>®</sup> and BD's Integra. Thus, the experience of a hospital-based user with retractable syringe technology was limited only to the Integra due to BD's exclusionary conduct and market power. As noted below, the poor design of the Integra causes it to leak, to prematurely collapse and in some instances allow the end to pop off, rendering its performance unsatisfactory.

53. Recently, Retractable sales personnel have received requests for the first time from hospitals for the 1 mL VanishPoint<sup>®</sup> products which have been available since 2000. The reason for some of these new inquiries was that early in 2009 BD voluntarily withdrew its 1 mL Integra product that it had marketed since about mid-2004. The design of the 1 mL Integra made the product difficult to activate from its inception. Substantial thumb force was needed to release the retraction mechanism of the 1 mL Integra and on information and belief BD had to increase that force further to have a saleable product. Although BD knew its product was essentially out of specification, BD kept it on the market for five years and only withdrew it because of Retractable's patent infringement suit.

54. In addition, Retractable sales personnel and Retractable management had to expend time and resources to correct BD's false statements and disparaging conduct about the VanishPoint<sup>®</sup> syringe product line. For example, BD has suggested to customers that the VanishPoint<sup>®</sup> syringes have severe splatter problems when, in fact, BD well knows that if used as directed by label instructions the VanishPoint<sup>®</sup> products have no splatter problems at all.

55. Retractable has expended resources after July 2004 to address what is essentially a made up "dead space" problem created by BD specifically to convince purchasers not to buy the VanishPoint<sup>®</sup> syringe. BD has overstated the amount of "dead space" or wasted medication that occurs when using a VanishPoint<sup>®</sup>. BD has also suggested that medical personnel can use the overage placed in medicine vials as expected wastage to squeeze an extra dose of medication from that vial if BD's Integra product is used. BD's suggestion does not advise customers of the wastage and leakage that plague the Integra designs.

56. These acts (and those described in more detail below), have foreclosed Retractable from a substantial portion of the relevant markets. For example, roughly two thirds

of the hypodermic syringe market is concentrated in the acute care (hospital) customer segment of the market. BD's products dominate this market segment, aided by exclusionary contracts obtained with the assistance of the powerful GPOs. In 2004 BD's market share for conventional syringes in the acute care market was around 80% and its safety syringe market share was about 62%.

57. When one considers that in 1999 BD conducted an extensive consumer survey that predicted that retractable syringes could become the largest selling type of hypodermic syringe products and yet that today only around 5% of hypodermic products are retracting syringes it is clear that consumer choice has not been satisfied and that a large portion of the overall market for hypodermic syringes has been foreclosed by BD's actions. The most efficient market segment for growth and distribution of hypodermic syringes is the acute care market and by foreclosing that key market segment the adoption of the superior safety of retractable syringes into the whole market has been delayed and defused.

58. The minimum efficient scale for production of a retractable syringe device is around 200 million syringes per year. Approximately two out of three syringes are used in acute care facilities. Therefore, in order to attain efficiencies in volume and provide lower pricing for the entire market, access to the acute care market is critical. That this critical market segment has been foreclosed is demonstrated by the difference in sales of units Retractable has experienced from 2004 to the present in the acute market as compared to the alternate care market segment. First, one would expect based on the two to one level of syringe usage in acute versus alternate care environments that sales to the acute care market would be twice those of alternate care. Instead, Retractable's current sales of units into the acute care market are about one sixth of the number of units sold into the alternate care market. In addition, while

Retractable has been able to increase its sales of units to the alternate care market by approximately 60% between 2004 and 2009, Retractable's sales of units into the acute care market from 2004 to 2009 have remained essentially flat because of BD's exclusionary contracts and other exclusionary conduct. If the acute care market had not been foreclosed to Retractable and Retractable had been able to sell a proportional number of units into the acute market based on its sales in the alternate care market, Retractable would be approaching the 200 million units a year efficiency level that would allow it to become a competitive force in the market.

59. On information and belief, the same level of foreclosure from the acute care market is true for Retractable's retracting safety IV catheter products. Even though Retractable's VanishPoint® safety IV catheters have been available since 2007 and priced approximately 30% less than BD safety catheters, Retractable has been virtually locked out of the acute care market.

60. More recently, Retractable introduced the Patient Safe™ syringe. Even though this product has been proven to avoid transmitting infections that are transmitted when a conventional syringe body is used and even though the Patient Safe™ syringe has been made available at the same cost as those inferior syringes, Retractable has been virtually locked out of the hospital market.

61. Retractable has been foreclosed from much more than 40% of the acute care product markets described above due to BD's exclusionary conduct. For example, since 2004 less than 10% of the approximately 5800 acute care facilities in the United States have purchased products from Retractable. In addition, regardless of the particular percentage, Retractable has been foreclosed from the acute care market which is the most efficient means of distribution and has been prevented from obtaining a sufficient amount of market share to undermine BD's monopoly in the market for hypodermic syringes and safety needle products.

### **BD Sees a Threat to Its Syringe Monopoly from New Demand for Safety Syringes.**

62. In contrast to Retractable's superior safety products introduced in the mid- to late-1990's, BD lacked innovative technology in the field of safety syringes. At the same time, the healthcare market demand for safety syringes was increasing dramatically. BD understood its vulnerability to Retractable. As noted above, in order to protect its position BD began to take unlawful exclusionary actions to copy Plaintiffs' patented technology, prevent and suppress Retractable's sales, and maintain and extend its dominance in the needle product markets. These unlawful actions by BD continue to the present day.

63. The legal environment for needle products began to rapidly change in 1999. On July 1, 1999, California's Needle Safety Law became effective. The Texas act became effective September 1, 1999. *See* TEX. HEALTH & SAFETY CODE §§ 81.301, *et seq.* On November 5, 1999, OSHA issued its Directive for Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens. On November 6, 2001, the federal Needlestick Safety and Prevention Act, P.L. 106-430 ("Needlestick Prevention Act") became law. The Needlestick Prevention Act requires healthcare employers to track needlestick injuries and to involve healthcare workers in selecting safer needle products. Since 1999, a number of other states also have enacted statutes to prevent needlestick injuries to healthcare workers. Beginning in 2001, OSHA regulations, codified at 29 C.F.R. § 1910.1030, have required hospitals and other medical facilities to track and report needlestick incidents and to involve front-line healthcare workers in annual reviews of safety programs and needle devices. The OSHA regulations also require that hospitals employ "engineering controls," defined to include "self-sheathing needles and safer medical devices such as sharps with engineered sharps injury protections," and to evaluate the available needle

products on the market and to select and use products that are effective in preventing needlesticks.

64. As a result of these statutes and the growing awareness of the needlestick problem, the healthcare industry needed and began to demand “safety” needle products.

65. Even though BD began to market product lines of needle products as “safe,” “safety,” or “safety-engineered,” those products were not safe. Rather, BD’s first alleged “safety” products incorporated nothing more than ineffective add-ons to BD’s conventional disposable syringe products. BD’s first alleged “safety” products were no safer than conventional syringes. In some ways, they are even more dangerous because they require a nurse or other healthcare worker to place a second hand in contact with the syringe after the needle is extracted from the patient to activate the alleged “safety” feature.

#### **BD Uses Marketing, not Safety, to Segment and Capture the Safety Syringe Market**

66. Desperate to meet the legislatively created demand for safety products, a demand that could have eliminated the entire market for conventional syringes that BD had monopolized for nearly a century, BD continued its reliance on outdated, unproven “safety” features and marketed product designs that appeared to provide safety but did not. A series of design decisions were driven by BD’s need to bring out so-called safety products quickly and at low cost. These designs were detrimental to the public because they created dangerous products. Worse, by marketing products as “safety” products without any basis for claiming they actually reduced accidental needlesticks, the products allowed healthcare industry purchasers to appear to comply with the serious safety requirements of the Needlestick Prevention Act. In fact, BD’s marketing strategy divided its safety syringe product offerings into three categories: (1) a compliance segment with products that would “comply” but would be clinically sub-optimal,

“war brand”-type products offered at the lowest possible cost (2) a “value” segment where some feature that was at least perceived as safe would be offered at a slightly higher price, and (3) a clinical feature segment for those customers willing to pay for what was thought to be the latest safety technology. BD developed the retractable BD Integra specifically to fill the clinical feature segment product offering.

67. BD’s decades long domination of the syringe market included use of and a large customer base for its syringe barrels to which detachable needles are affixed for use. BD had long promoted “needle changing” by nurses. Nurses had been taught that pushing a needle through the top of a rubber vial would dull the needle so that it should be discarded and a fresh “sharp” needle used on the patient. In order to extend and prolong this profitable bit of nursing lore, BD designed every safety syringe product it could to use detachable needles, even in the face of CDC advice not to change needles because of the risk of sticks and contamination.

68. BD introduced what it called the first safety syringe product in the 1980’s, after purchasing the design for a sliding tube-like shield from a nurse. That design fit over the standard BD syringe body and could use BD’s normal changeable needles.

69. As BD scrambled to expand its safety syringe line-up and use the designs to segment, conquer and monopolize the growing safety syringe market, it engaged in market driven design activities that continue today and that harm the public in ways that far outweigh any possible pro-competitive justification.

70. Continuing with a design used in its first attempted safety product that BD knew was both dangerous and ineffective, BD designed so-called safety features that require the user to move a hand or finger (or both) closer to the contaminated needle than is necessary when using a conventional, non-safety syringe. The requirement for user motion toward the

contaminated needle tip in order to shield or cover it is an obvious design flaw that BD should have known would (and has proven to) increase, not decrease, needlestick injuries, the majority of which occur within moments of use.

71. BD's first generation alleged "safety" syringe mentioned above was the "Safety-Lok." The Safety-Lok contains an outer sleeve that a user must slide over the needle after an injection is complete and the needle is withdrawn from the patient. To operate this mechanism a user must use both hands, one to hold the syringe and the other to slide the sleeve from its position around the barrel to its extended position over the needle. This places the user's free hand at an increased risk of contacting the exposed, contaminated needle. BD's Safety-Lok mechanism is not automatic. It requires a user to actively cover the needle of the syringe. If a user takes no action, the needle remains exposed and the syringe is more bulky, harder to manipulate and no safer than a conventional syringe. It also requires more space in a sharps container, increasing costs and risks of disposal.

72. BD has maintained the Safety-Lok in the market from 2004 to the present even though it knows the product to be ineffective and dangerous. BD knows that many customers never attempt to activate the product by sliding the tube up – choosing to just dispose of the product and not risk injury through activation. BD has maintained the Safety-Lok on the market because it can offer it at low cost to its compliance market segment as a "safety product", even though there is no evidence that the product is actually safe and direct evidence that use of the product can and does increase needlesticks.

73. BD's second generation alleged "safety" syringe was the "SafetyGlide." The SafetyGlide incorporates a small hinged lever between the base of the needle and the pointed tip that, when pressed forward, extends a cover over the needle tip. Activation can only occur after

the contaminated needle is removed from the patient. Like the Safety-Lok, a nurse or doctor must, after injecting a patient, reach down to the syringe to engage the lever. This action again places the user's hand in close proximity to the contaminated needle, thereby increasing the risk of a needlestick injury. Like the earlier Safety-Lok, BD's SafetyGlide requires a user to take an additional physical action to press the hinged lever before the safety device engages.

74. In addition, the SafetyGlide design allows its front mounted needle to spin off the syringe during or after use. The design element that allows the needle portion of the Safety-Glide needle to torque, loosening it on the end of the syringe barrel, is a problem well known to BD, who continues to offer the product to the market as its intermediate price value segment. There have been frequent reports since 2004 that the safety feature on the SafetyGlide from time to time would simply fall off the syringe, thereby exposing the contaminated needle.

75. Another alleged "safety" syringe marketed by BD is the "Eclipse," which features a hinged shield at the base of the needle that can be pivoted to cover the needle. After injecting a patient, a user must withdraw the needle from the patient, reach down to the exposed, contaminated needle, and flip the Eclipse shield into place by hand or place the syringe with its exposed needle on a table-top or other firm surface against which the shield can be flipped into place. Flipping the shield into place also can throw blood and/or aerosolized fluids from the needle and onto healthcare providers, patients, or surrounding surfaces.

76. The Eclipse is a form of a product design rejected by BD but later brought out as a war brand in order to supplement the Safety-Lok product line for the compliance market segment. BD continues to market this product though it knows that the product still has the design elements that can cause torque during activation that can cause the needle to fall off and that users often do not activate the shield at all.

77. BD's Integra retractable syringes were supposed to serve the clinical feature segment of BD's market plan; that is, the highest cost products that clinicians perceived as delivering real safety. BD developed the Integra retractable syringe after it bought an unworkable design from a company called Safety-Med and reworked the design to incorporate the patented innovations of Thomas J. Shaw. While BD copied Shaw's patented inventions into the Safety-Med design to get a product that worked at all, its re-design incorporated features that would provide sales point distinctions but at the cost of lost safety and performance. Thus, BD designed the 3 mL Integra to have a changeable needle, low dead space, and the ability to be activated outside the patient. While BD may have considered that these "features" would make for good advertising distinctions, the CDC advised against changing needles, and medication suppliers accounted for small wastage by slightly overfilling their vials. Further, BD did not mention in its sales literature that changing needles would lose the medication savings the reduced dead space feature was supposed to provide. In addition, activating the needle outside the patient caused splatter and the exact kind of dangers the Needle Stick Prevention Act was designed to reduce.

78. The attempt to provide the Integra with a changeable needle resulted in design elements that are dangerous to the public and far outweigh any legitimate need for a changeable needle design. BD's main impetus for a changeable needle design was (1) to perpetuate BD's encouragement for users to wastefully use more needles at the expense of risking contamination by opening the syringe after drawing up sterile medication and (2) to provide a sales distinction that could be used to discourage purchase of Plaintiffs' VanishPoint<sup>®</sup> syringes that only offered fixed needles. BD is well aware of the leakage and pop-off risks for the 3 mL Integra and has delayed and cancelled numerous internal calls for a re-design to attempt to fix the problem.

Recently the CDC, when instructing health care workers on H1N1 vaccination procedures, warned workers of reliable reports of leakage problems with the 3 mL Integra. BD itself sent out a special mailer in late 2009 reminding users to tighten the needle on the Integra before use to avoid leakage. BD has no legitimate business reason to maintain the Integra in the marketplace with these known problems except to continue to block Plaintiffs' VanishPoint<sup>®</sup> products.

79. BD also knows that the Integra 3 mL is unsuitable for use with certain common medications due to a condition called premature plunger rod collapse wherein the telescoping design of the plunger collapses before all medication is delivered. This condition when it occurs can cause under-dosing and an unexpected non-retraction of the needle that can lead to needle stick injury. Again, BD well knows about this problem but maintains the product in the market, putting the public at risk so it can use the Integra to block widespread adoption of Plaintiffs' VanishPoint<sup>®</sup> products.

80. Another instance of design decisions that BD made in order to rush a retractable syringe to market to block Plaintiffs' products was its decision to allow the Integra to be activated outside the body. BD has advertised this feature as an "advantage" when in truth it is a cover-up for a design flaw and is dangerous to the public. The basic design BD purchased required use of a cutter that cuts through a diaphragm to release a frictional hold and allow needle retraction to occur. Having to cut to operate increased required thumb force and required that a small diameter spring be used to keep the cutting forces as low as possible. A small spring diameter resulted in a weak spring force, which was too weak to reliably pull the needle out of the human body. To cover this defect, BD recommends that the user activate the spring when the needle has been manually withdrawn from the patient. First, this defeats most of the safety provided by automatic retraction since statistics show that a majority of accidents occur in the

first few seconds after withdrawal. Second, when this is done the spring action causes significant splatter of fluids from the tip of the needle and syringe. While reducing contact with such fluids is a main objective of safety products, BD, without adequate testing or basis, decided to place the Integra 3 mL on the market with a small warning about splatter on its packaging.

81. Thus, in addition to leakage and premature plunger rod collapse, the 3 mL Integra is difficult to activate, causing users to activate it outside the body and causing spray or splatter. Since the Integra is often the only non-RTI retractable syringe available, its poor and dangerous performance from 2004 to present has severely tainted the market against Plaintiffs' products that are easy to activate and, when used as directed by activating in the body, have no splatter.

82. BD's 1 mL Integra did not have a changeable needle nor a collapsing plunger, but it suffered from the same types of 3 mL Integra design flaws noted above regarding difficulty to activate and splatter problems. The 1 mL Integra was introduced in 2004 and withdrawn in 2009. Not only was the 1 mL an infringement of Plaintiffs' patents, but also, as BD knew, it never was produced within specification and did not satisfy customers because it was too hard to activate. BD re-designed the 1 mL Integra in 2004 to solve an operability problem and despite clinical testing that showed a preference for the early design over the "fix" that caused it to be harder to activate, BD re-designed the 1 mL to be harder to activate. It kept this flawed product on the market for five years in order to block Plaintiffs' VanishPoint<sup>®</sup> products from the market. In particular, BD used the existence of the Integra products to attract customers to contracts that drove sales of its other syringe products.

### **BD Covers Up Evidence of Flawed Designs in Order to Expand and Maintain Its Monopoly**

83. On information and belief, BD failed to conduct proper clinical testing in its rush to design, produce and market safety syringe products. On information and belief, an external

auditor was hired as a result of a complaint by a high BD official regarding the inadequacies of BD's internal data management system to adequately track results from clinical trials. In part, the auditor's report, issued about November 2004, stated:

[T]he current BD culture has fostered an environment in which meeting established timelines for product development and delivery takes precedence over ensuring that clinical trials are conducted in accordance with applicable regulations and established scientific methodologies. Of additional concern, is the perception that full regulatory compliance is not required of BD operations and is necessary only for those companies in which an FDA inspection is likely to occur (i.e. high risk device) and therefore allows for unmanaged leeway when conducting clinical trials.

84. Thus, rather than properly test its safety syringe products and comply with all FDA requirements, BD, in order to obtain, maintain and/or expand its hold on the safety syringe market continued to market products it knew were unsatisfactory in performance. For example, numerous calls for re-design of its Integra syringes were shelved and those products were kept on the market so that BD could claim it had a retractable syringe and thereby exclude competitors such as Retractable from gaining market share with superior retractable products.

**BD Engages in False Advertising to Maintain and Expand its Monopoly.**

85. BD has conducted ongoing and extensive campaigns of deceit in its advertising and promotional tactics, designed and executed to create and maintain anticompetitive barriers to market entry for innovative non-BD technology after July 2, 2004. BD's deceptions are false and misleading, longstanding, material, and relied on by consumers. The nature of BD's false advertising, in general, and disparagement of Retractable's products, in particular, in conjunction with BD's control not only of the market but also of direct access to purchasers, has made it difficult and costly for Retractable to counter BD's false and misleading claims.

86. Because of BD's hundred-plus-year history in healthcare and its representations that it has "data on file" to support its claims, its false, misleading and disparaging advertising and promotion was likely to induce, and did induce, reasonable reliance by the public and customers, who were without knowledge as its veracity. Further, the misrepresentations were not readily susceptible to neutralization by BD rivals, such as Retractable who, because of BD's market dominance and exclusionary contracts and conduct, cannot get a hearing from customers much less make the sales its innovative products deserve.

87. Many individual examples of BD's advertising are false standing alone, and many more are false or misleading when considered in context—as all advertising must be by law. Although it is impractical to catalog each and every instance of BD false advertising and disparagement, representative species of the major types are discussed below.

88. **Dead space, dose accuracy, and medication savings.** Upon completion of a medication injection, all syringes contain a small amount of residual medication left behind in the syringe tip, needle hub, and cannula. The volume of residual medication, which varies from design to design, is known as the residual space, waste space, or dead space.

89. Dead space should not affect dose accuracy because the dose measurements on a syringe barrel are calibrated to account for the dead space of that particular design.

90. Likewise, a syringe that meets ISO standards for dead space should get the recommended number of doses from a medicine vial, because manufacturers over-fill single- and multi-dose vials to account for standard dead space.

91. Faced with the commoditization of its primary revenue source, BD long-ago developed a "med-saver" strategy targeting dead space as a potential differentiator for some of its syringes. BD's basic pitch to consumers is that lower-dead space syringes can drive down

per-dose costs. In theory, this works one of two ways. First, with a small enough dead space and a large enough multi-dose vial, one might extract “extra” doses from a vial, e.g., eleven doses from a ten dose vial. Second, one could combine left-over over-fill from many vials to extract “extra” doses from multiple vials, e.g., the over-fill from ten single-dose vials could be combined to make up an eleventh dose. However true in theory, BD’s advertising based on this idea, taken in context, is deliberately and literally false and misleading, explicitly targeted at Retractable’s VanishPoint® syringes, and over-states VanishPoint®’s dead space by 200%.

92. For example, BD promoted its Integra with web-based advertising explored via links (“Integra Links”) at the top of each web-page in the Integra ad series, which from about August 2005 to March or early April 2010 appeared like this:

[About BD Integra™ Retracting Syringes](#) | [3 mL Syringe Attributes](#) | [1 mL Syringe Attributes](#) | [How Waste Space Impacts Drug / Vaccine Supply](#) | [Maximizing Your Influenza Vaccine Supply](#) | [Medication Savings At A Glance](#) | [Cost Calculator](#) | [FAQs](#) | [Literature/Ordering Information](#) | [Request More Information](#)

93. In about April 2010, the “1 mL Syringe Attributes” link was dropped (although the ads that it led to remained elsewhere on BD’s web site) so that the Integra Links were so:

[About BD Integra™ Retracting Syringes](#) | [3 mL Syringe Attributes](#)  
[How Waste Space Impacts Drug / Vaccine Supply](#) | [Maximizing Your Influenza Vaccine Supply](#)  
[Medication Savings At A Glance](#) | [Cost Calculator](#) | [FAQs](#)  
[Literature/Ordering Information](#) | [Request More Information](#)

94. Each ad reached through the Integra Links provides context for the others. Thus, for example, the context for interpreting references to “Brand A Retracting Syringe” in one ad include, at least, (1) the VanishPoint® drawings labeled “Brand A Retracting Syringe” in one linked ad, (2) the data about “Brand A Retracting Syringe” in another linked ad, and (3) the references to “RTI Vanishpoint [sic] 3 mL Retracting Syringe” in still another of the linked ads.

95. The first Integra Link, “[About BD Integra™ Retracting Syringes](#),” leads to the address <http://www.bd.com/hypodermic/products/integra/> (the “About BD Integra page”), which bears the Integra Links, depicts an Integra 3 mL syringe, and depicts these claims among others:

**About BD Integra™ Retracting Syringes**



***Low Waste Space... Maximize Medication... Experience It!***

What sets the BD Integra™ Syringe apart from other syringes on the market? Its design. The BD Integra™ Syringe with Retracting BD PrecisionGlide™ Needle was designed to provide clinicians with superior clinical benefits.

- Detachable Needle\*
- Low Waste Space\*
- Dosing Accuracy\*
- BD PrecisionGlide™ Needle Technology\*

View video of 3mLBD Integra™ Syringe:  
[Windows Media® Player](#)

\* Data on file

96. The claims that Integra’s “dosing accuracy” is superior to other syringes on the market and that BD has data proving it are literally false and misleading.

97. As discussed further below, the claims that Integra 1 mL syringe features a detachable needle and that BD has “data on file” to show “superior clinical benefits” due to (1) detachable needles and (2) “BD PrecisionGlide™ Needle Technology” (used interchangeably with a claim for the “World’s Sharpest Needle”) are also misleading or literally false.

98. Clicking “[3 mL Syringe Attributes](#)” in the Integra Links leads to these claims at [http://www.bd.com/hypodermic/products/integra/attributes\\_3mL.asp](http://www.bd.com/hypodermic/products/integra/attributes_3mL.asp) (“3 mL Attributes page”):

**Low Waste Space\***

Compare BD Integra™ 3 mL Syringe's .026 mL of waste space volume to BRAND A 3 mL retracting syringe which has .185 mL of waste space volume. Over time, syringe designs with high waste space volume may adversely impact a healthcare facility's bottom line.



BD Integra™  
3 mL Syringe  
.026 mL



Brand A 3 mL Retracting  
Syringe  
.185 mL

BD Integra™ Syringe waste space volume is **86%** lower than Brand A Retracting Syringe.

View product video:  
Windows Media® Player

The BD Integra™ Syringe design *minimizes* the waste space area to *maximize* the number of doses a clinician is able to aspirate from a multi-dose vial. View the [medication savings](#) experienced with BD Integra™ Syringes.

**Detachable Needle\***

It's the only spring-based 3 mL retracting syringe on the market with a detachable needle. Detachable needle offers clinical flexibility, allowing clinicians to change needles for aspiration and administration.

**Dosing Accuracy\***

The BD Integra™ 3 mL Syringes deliver the complete medication dose, whether the user activates the device before or after the needle is withdrawn from the patient.

\* Data on file

99. The drawings on the 3 mL Attributes page depict BD's Integra 3 mL syringe (so identified) and Retractable's VanishPoint® 3 mL syringe (labeled "Brand A 3 mL Retracting Syringe"). No syringe on the market other than VanishPoint® looks like the "Brand A" picture. When the ad was first published, VanishPoint® and Integra were the only two "spring-based" retracting syringes on the market, and VanishPoint® was the only 3 mL retracting syringe marketed without a detachable needle.<sup>1</sup> The drawing and these facts—plus the linking of this ad

<sup>1</sup> New Medical Technologies, Inc. stopped making its NMT Safety Syringe—which had a distinctly different profile than the Brand A depiction—in 2003. The OMI Retractable Safety Syringe had an equally distinct profile, was only briefly sold by Cardinal Health after this lawsuit was filed, was originally made long after this ad first appeared, and

to the Cost Calculator that calls out VanishPoint® by name—show BD’s intent to portray “Brand A” as the VanishPoint®.

100. For the entire time relevant to this suit, the actual dead space on the VanishPoint® 3 mL syringe has been about 0.06 mL—a third or less of the 0.185 mL claimed in this BD advertisement. Thus, the 3 mL Attributes page is literally false and misleading as to (1) the VanishPoint®’s actual dead space and (2) whether BD “data on file” establishes what is claimed.

101. The VanishPoint® 3 mL syringe delivers as accurate and complete a dose as the BD Integra 3 mL syringe. However, the 3 mL Attributes page falsely suggests that, because of its dead space, VanishPoint® does not deliver an accurate or complete dose. These claims are false and misleading, and BD does not have data on file accurately linking dead space to dose accuracy or showing that the BD Integra yields more accurate doses than the VanishPoint®.

102. Clicking on the “medication savings” link imbedded in the sentence “View the medication savings experienced with BD Integra™ Syringes” takes the reader from the 3 mL Attributes page to [http://www.bd.com/hypodermic/products/integra/medication\\_savings.asp](http://www.bd.com/hypodermic/products/integra/medication_savings.asp) (“Medication Savings page”) also reachable by clicking [Medication Savings At A Glance](#) in the Integra Links at the top of each page in this series of advertisements.

103. Presented in context with the Cost Calculator, which calls out VanishPoint® by name, and with other ads that depict VanishPoint® as “Brand A Retracting 3 mL Syringe,” the Medication Savings page conveys more false information—based on grossly false dead space data—about the costs of using VanishPoint® versus Integra and BD’s conventional syringe:

---

looked nothing like the Brand A drawing. BD designed Integra with a detachable needle for the express purpose of marketing that “feature” against VanishPoint®.

### Medication Savings At A Glance

Treat more with less. You can with the BD Integra™ Syringe. Its reduced waste space volume maximizes your vaccine supply and lets you treat more people and save money. And because everything counts, that adds up.

	BD Conventional 3 mL Syringe		BD Integra™ 3 mL Syringe		Savings Per Dose Using BD Integra™ Syringe
Drugs/Vaccines	Doses/Vial	Cost/Dose	Dose/Vial	Cost/Dose	
Haldol®	36.0	\$2.09	46.5	\$1.61	<b>\$0.48</b>
Influenza	10.0	\$8.53	11.2	\$7.58	<b>\$0.95</b>
Pneumococcal	4.5	\$21.64	5.1	\$19.23	<b>\$2.41</b>
Tetanus	9.0	\$15.61	10.1	\$13.87	<b>\$1.74</b>
Zofran®	9.8	\$26.04	10.2	\$25.22	<b>\$0.82</b>
TB	6.5*	\$3.86	10.6**	\$2.36	<b>\$1.50</b>
	Brand A Retracting 3 mL Syringe		BD Integra™ 3 mL Syringe		
Drugs/Vaccines	Doses/Vial	Cost/Dose	Dose/Vial	Cost/Dose	
Haldol®	27.3	\$2.75	46.5	\$1.61	<b>\$1.14</b>
Influenza	8.6	\$9.87	11.2	\$7.58	<b>\$2.29</b>
Pneumococcal	3.9	\$25.04	5.1	\$19.23	<b>\$5.81</b>
Tetanus	7.7	\$18.06	10.1	\$13.87	<b>\$4.19</b>
Zofran®	9.4	\$27.20	10.2	\$25.22	<b>\$1.98</b>
TB	8.7***	\$2.86	10.6**	\$2.36	<b>\$0.50</b>

\* Using a 1 mL Conventional Syringe with Detachable 27G Needle

\*\* Using 1 mL BD Integra™, TNT or BD Safety-Lok™ 27G Syringe

\*\*\* Using 1 mL Brand A 27G Retracting Syringe

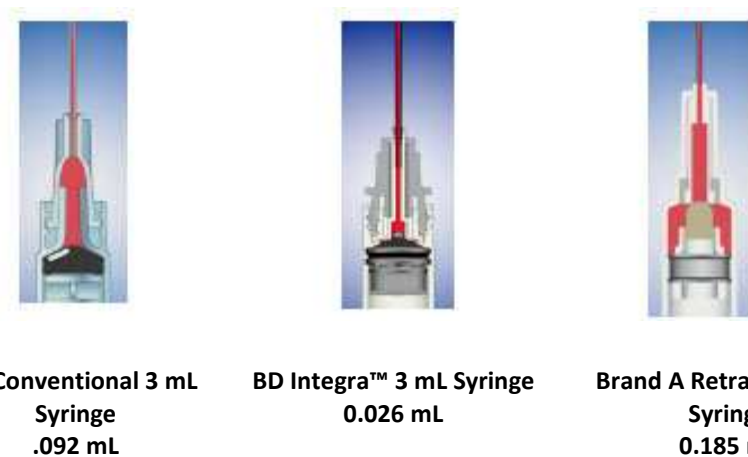
104. Retractable's VanishPoint® dead space of 0.06 mL is about 33% less than a BD's conventional syringe dead space of 0.092 mL; however, the Medication Savings page falsely teaches that the VanishPoint®'s dead space is greater than that of a BD conventional syringe and that the VanishPoint® will, therefore, draw fewer doses per vial.

105. Although the Medication Savings page does not, on its face, state "data on file," the authoritative presentation of precisely measurable data—linked to pages addressing related data and boasting of "data on file"—falsely suggests that BD has tests and data that establish these claims. BD has no such tests.

106. The false dead space comparison to Integra and conventional syringes is made explicit and pictorially-linked to VanishPoint® on another ad in this series, reached through the top-of-the-page Integra Link, “[How Waste Space Impacts Drug / Vaccine Supply](#),” which leads to [http://www.bd.com/hypodermic/products/integra/wastespace\\_impacts.asp](http://www.bd.com/hypodermic/products/integra/wastespace_impacts.asp) (the “Waste Space Impacts page”). The Waste Space Impacts page depicts the following:

The BD Integra™ Syringe allows clinicians to utilize a greater proportion of the over-filling for actual medication dosing. These extra doses can greatly reduce costs and stretch a greater number of vaccinations from existing vaccine supply.\*

**The BD Integra™ Syringe has up to 86% less waste space volume**



***Note: Red area represents waste space volume***

\* Data on file

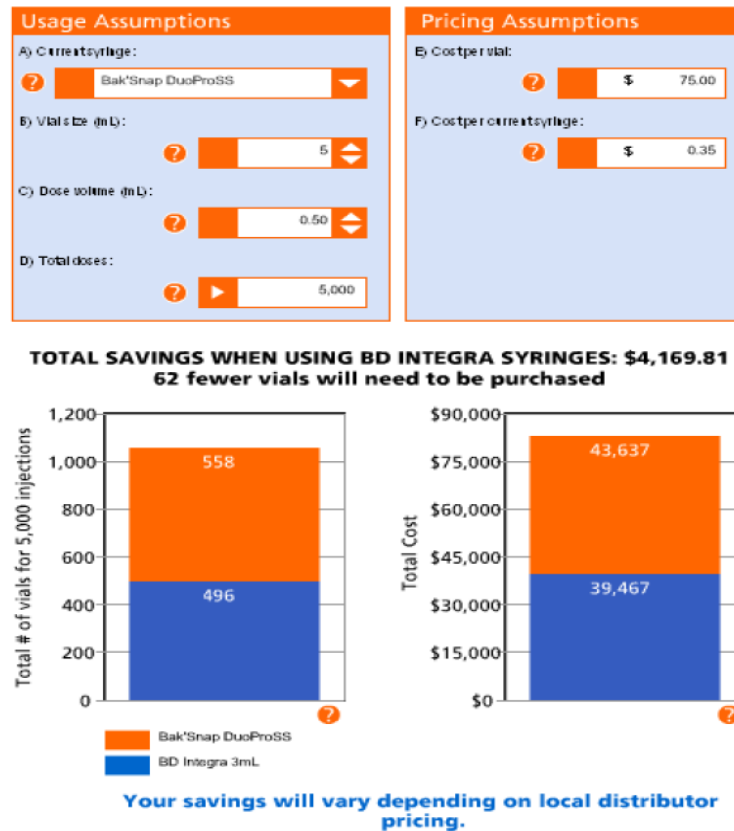
107. The Waste Space Impacts page again depicts the VanishPoint®, labeled as “Brand A Retracting 3 mL Syringe” and misrepresents its dead space both in actual and relative terms. The actual dead space on the VanishPoint® 3 mL is—and for many years has been—0.06 mL, but the ad shows it as three times that amount.

108. Clicking on “[Cost Calculator](#)” in the Integra Links takes the viewer to the address [http://www.bd.com/hypodermic/products/integra/cost\\_calculator.asp](http://www.bd.com/hypodermic/products/integra/cost_calculator.asp) (the “Cost Calculator”) an interactive site that initially shows this information:

### Cost Calculator

The BD Integra™ Syringe helps you extend your vaccine supply - which means you can treat more patients and save money. To get an idea of just how much you can save by using the BD Integra™ Syringe, just use this simple medication savings calculator.

- From the pull down menus, select the following:
  - Current Syringe Brand/Size In Use
  - Medication/Drug Vial Size (Choose from: 1mL, 2mL, 5mL, 10mL, 20mL, 30mL)
  - Dose Volume (mL)
- Then, fill in each of the required fields:
  - Number of Doses
  - Cost Per Medication/Drug Vial
  - Cost Per Current Syringe Brand In Use



109. The viewer is further instructed as follows:

Once all the information is entered, the cost savings of using the BD Integra™ Syringe versus your current syringe brand will automatically appear, as well as how many vials of medication you will need to purchase when using the BD Integra™ Syringe versus your current syringe brand.

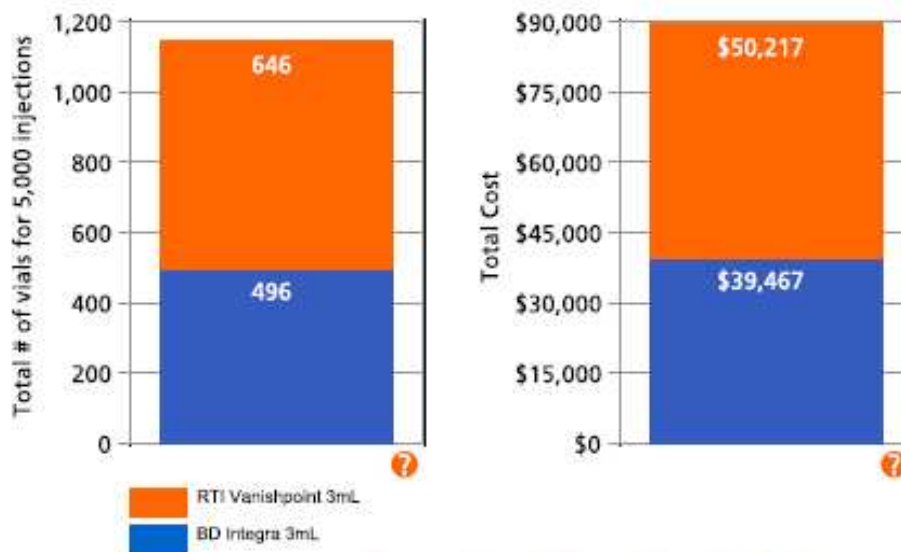
Depending upon your local distributor's pricing, the actual cost savings when using the BD Integra™ Syringe could be even higher!

Experience it!

110. Picking “RTI Vanishpoint 3mL Retracting Syringe” for “Current syringe” yields:

Usage Assumptions		Pricing Assumptions	
A) Current syringe:	<input type="text" value="RTI Vanishpoint 3mL"/>	E) Cost per vial:	<input type="text" value="\$ 75.00"/>
B) Vial size (mL):	<input type="text" value="5"/>	F) Cost per current syringe:	<input type="text" value="\$ 0.35"/>
C) Dose volume (mL):	<input type="text" value="0.50"/>		
D) Total doses:	<input type="text" value="5,000"/>		

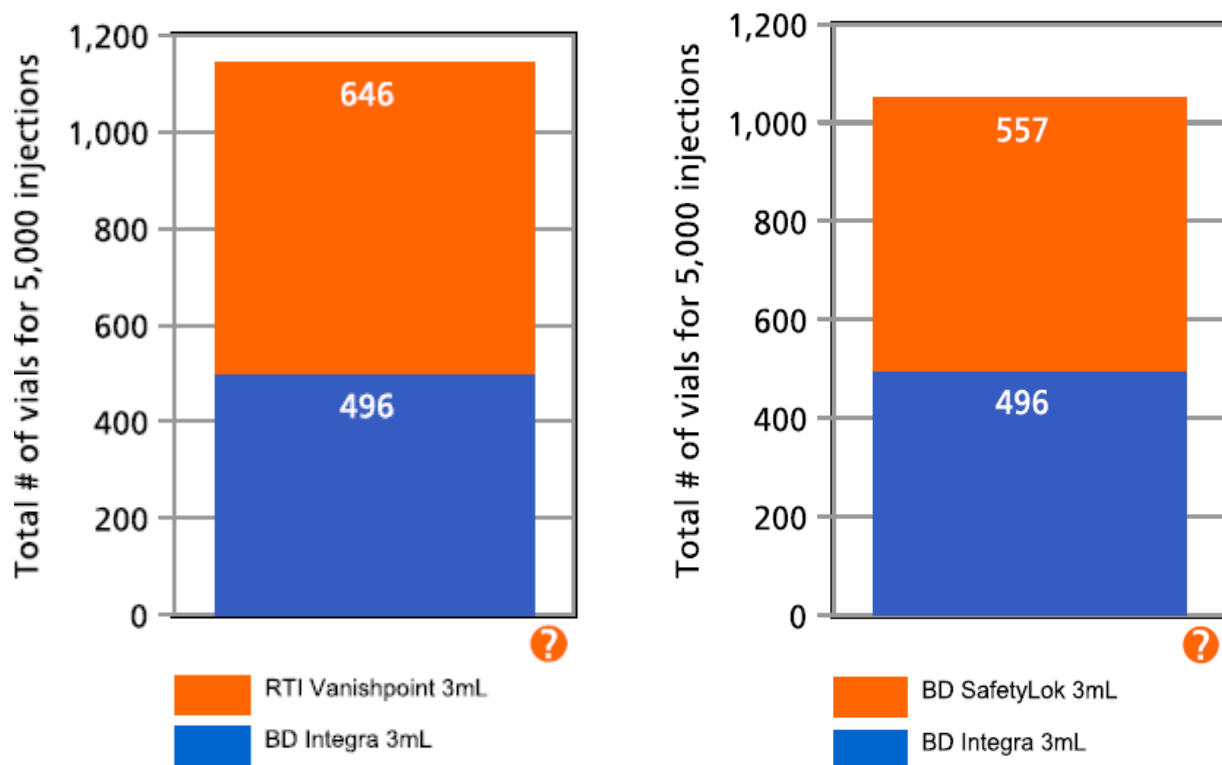
**TOTAL SAVINGS WHEN USING BD INTEGRA SYRINGES: \$10,750.00**  
**150 fewer vials will need to be purchased**



**Your savings will vary depending on local distributor pricing.**

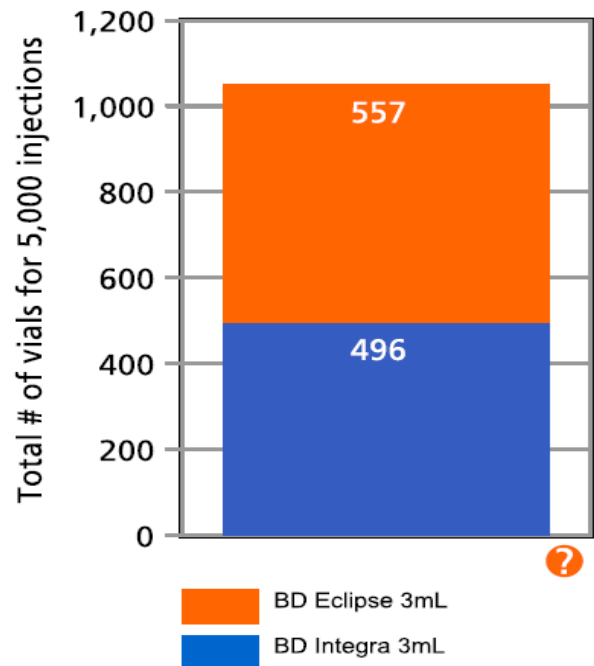
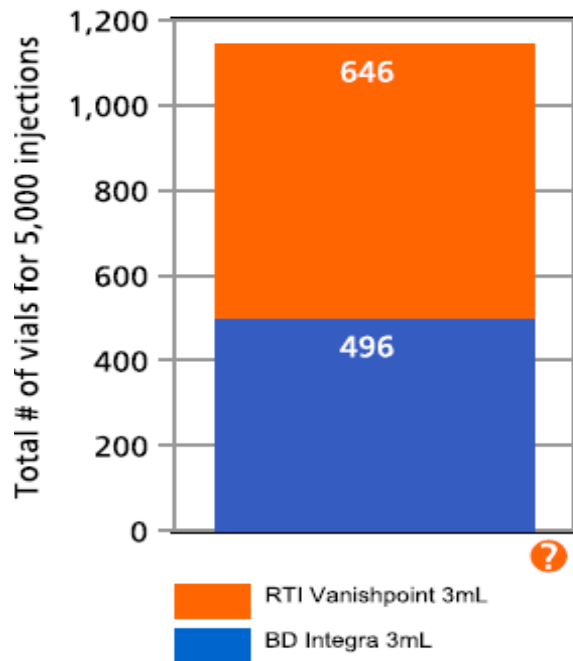
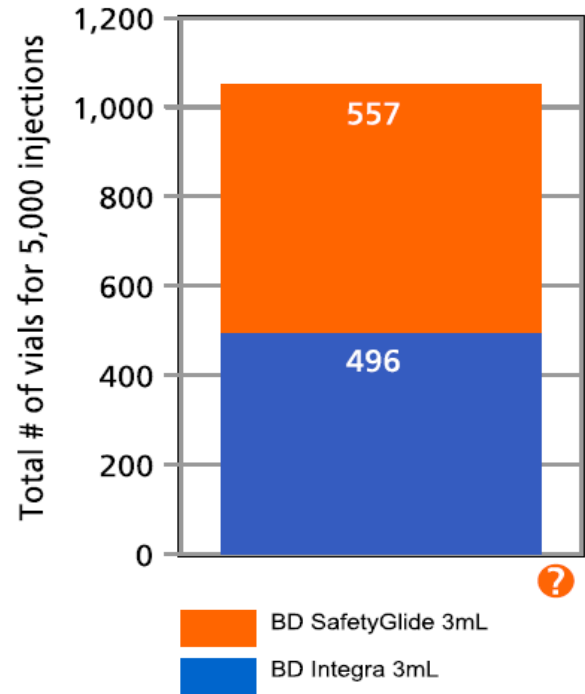
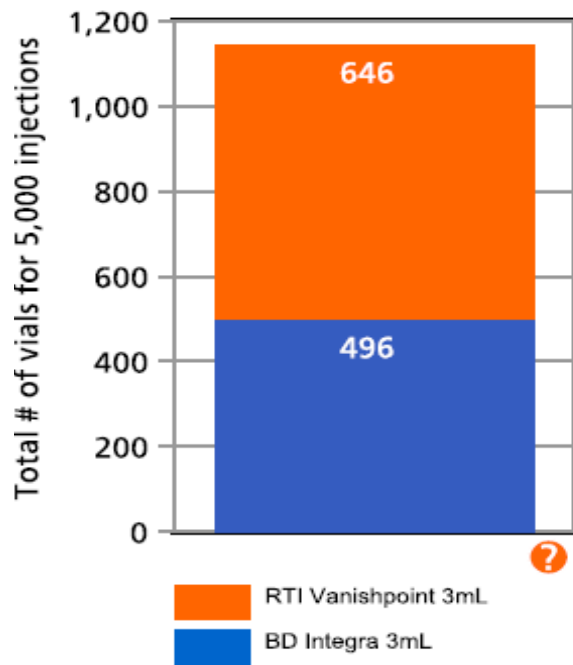
111. This comparison of the VanishPoint® to the Integra is false and is based on the 0.185 mL dead space depicted in the ads described above—which is three times VanishPoint®’s actual dead space. Further, the Cost Calculator allows the user to run this same comparison with other competing syringes against Integra—which effectively allows a false comparison of VanishPoint® to almost every syringe on the market.

112. For example, one can run comparisons with all of BD's competing conventional and safety syringes against the Integra and compare those results to the VanishPoint® results. Comparing the result for RTI Vanishpoint [sic] 3mL versus BD Integra 3mL to BD SafetyLok [sic] 3mL versus BD Integra 3mL yields:



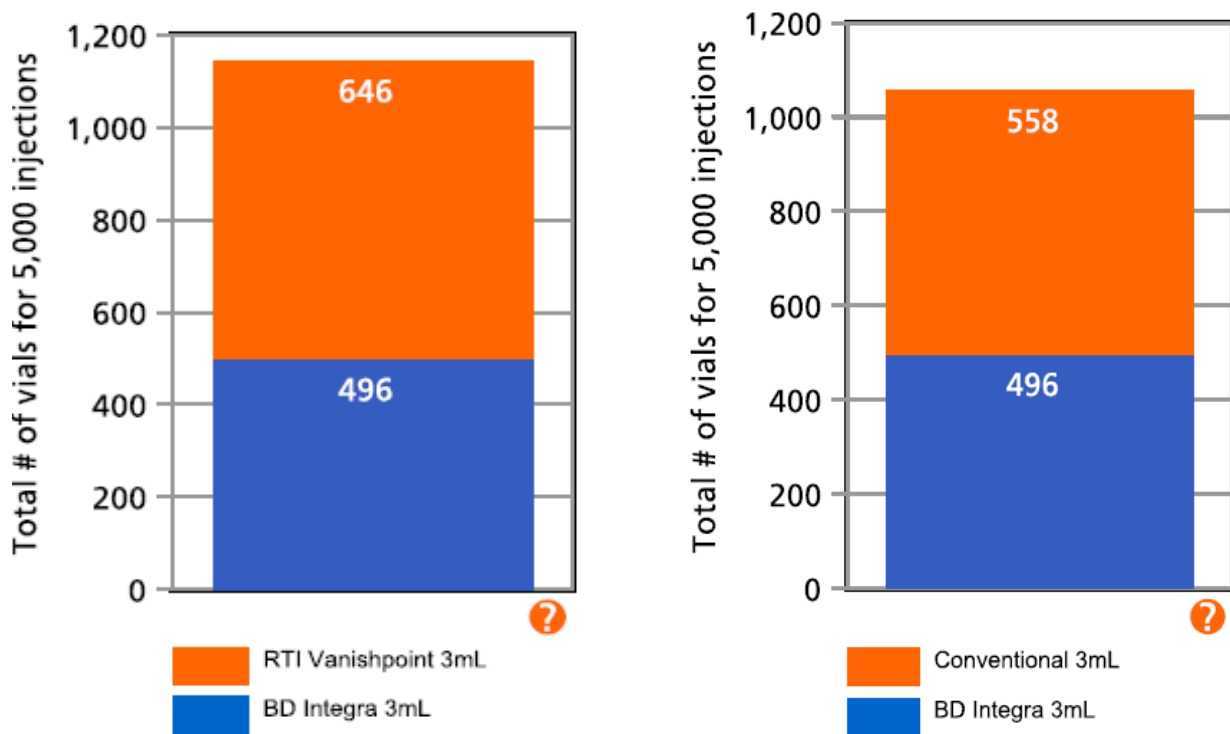
113. Thus, the Cost Calculator falsely instructs that, for the same number of doses, the VanishPoint® requires more vials (646 vials, see image above on the left) than the Safety-Lok (557 vials, see image above on the right). In fact, the VanishPoint® would require fewer vials because its dead space is about two thirds that of the Safety-Lok 3 mL syringe.

114. Results for BD's SafetyGlide and Eclipse are equally, literally false:



115. Like Safety-Lok, the SafetyGlide and Eclipse are conventional syringes and needles with a piece of plastic added to the outside to cover the needle. Because there is no internal change to the syringe/needle combination, the dead space of these BD “safety” designs is like that of BD’s conventional syringe and needle. Thus, for example, in the 3 mL size, the VanishPoint®’s dead space, being two thirds that of a conventional syringe, is also two thirds that of the Safety-Lok, SafetyGlide and Eclipse. But the BD Cost Calculator falsely teaches that the VanishPoint®’s dead space is more than each of these competing, inferior products.

116. The lies told in the Waste Space Impacts page and the Medication Savings page about VanishPoint® versus a BD conventional syringe reappear in the Cost Calculator:



117. In the Cost Calculator and the other Integra Links, BD represents—and represents that it has tests establishing—that the dead space of the VanishPoint® 3 mL syringe is greater than all BD syringes, is 0.185 mL, and causes more costs in medication and related expenses

compared to BD products and others. These intentionally false and misleading statements of material fact were used in interstate commerce, were calculated to deceive, have deceived, or have tended to deceive, consumers, and have harmed Retractable.

118. On or about August 2, 2005, BD issued a press release that “announced the launch of an online resource to help educate clinicians and medical care facilities on how dose-sparing injection devices can help them maximize their flu vaccine supplies: [www.bd.com/Integra](http://www.bd.com/Integra).”<sup>2</sup> The [www.bd.com/Integra](http://www.bd.com/Integra) address currently opens to the above-described About BD Integra page, that is, <http://www.bd.com/hypodermic/products/integra/>, which includes the Integra Links. Upon information and belief, the Integra Links ads were first-published as part of the announced “online resource” and have been false and misleading since their first publication.

119. Each of the above-described ads presently bears a copyright date (e.g. “© 2010 BD”) that has been updated each year since first publication. Thus, BD has not only re-published the false and misleading claims each year but also represented them to consumers as current for each year. Although the qualities of the depicted syringes have changed over the life of the ads, the ads have not been updated, and BD’s “data on file” has not been updated and does not establish what the ads claim for every—or, as to VanishPoint®, for any—year at issue.





120. More links within the Integra Links ads lead to still more false ads, e.g., the link, “BD Integra™ Syringe Literature and Ordering Information,” in the 3 mL Attributes page leads to: [http://www.bd.com/hypodermic/products/integra/literature\\_ordering\\_info.asp](http://www.bd.com/hypodermic/products/integra/literature_ordering_info.asp) (the “Literature Ordering Info page”), which, in turn, contains groups of links to pdf-formatted documents.

---

<sup>2</sup> [http://www.bd.com/press/pdfs/dose\\_sparing\\_injection\\_devices.pdf](http://www.bd.com/press/pdfs/dose_sparing_injection_devices.pdf)

121. One group of four links is identified as “White Papers” and appears as follows:

**White Papers:**

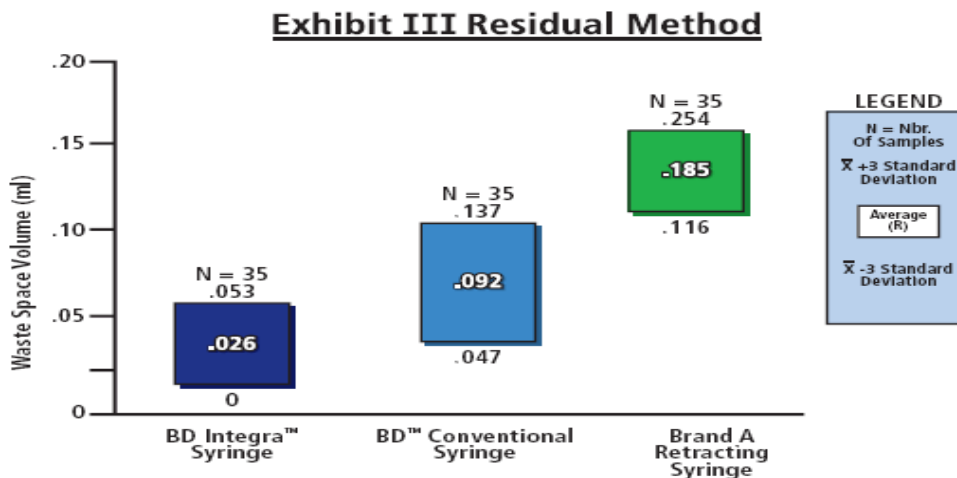
- ["Maximizing Prophylaxis, Making the Most During the '04-'05 Influenza Vaccine Shortage," Dept. of Pharmacy, Mt Sinai Medical Center New York, NY](#) 
- [Evaluation of the BD Integra™ Syringe at Texas Childrens Hospital and Test-med](#) 
- [Wastespace Syringe Design: The Impact of the BD Integra™ Syringe On Medication Savings](#) 
- [Report on the Evaluation of the Improved BD PrecisionGlide™ Needle, "The Worlds Sharpest Needle"](#) 

122. The fourth White Papers link, “Report on the Evaluation of the Improved BD PrecisionGlide™ Needle, ‘The World’s Sharpest Needle,’” leads to a description of a study that BD repeatedly references in ads that make the “World’s Sharpest Needle” claim, which, as discussed in detail later in this Second Amended Complaint, is false.

123. The third White Papers link is to a “Low Waste Space White Paper”<sup>3</sup> that repeats the lie that BD “data on file” shows .185 mL dead space for “Brand A Retracting 3ml Syringe:”

**Results:**

The Waste Space volume test results, using the Residual Method, for the BD Integra™ 3ml Syringe, BD™ Conventional 3ml Syringe and Brand A Retracting 3ml Syringe are illustrated in Exhibit III. (data on file)



124. The Low Waste Space White Paper also describes tests supposedly used to establish its .185 mL dead space claim and other data—thus giving the veneer of science to false

<sup>3</sup> [http://www.bd.com/safety/pdfs/Low\\_Waste\\_Space\\_whitepaper\\_0554.pdf](http://www.bd.com/safety/pdfs/Low_Waste_Space_whitepaper_0554.pdf)

claims directed at the VanishPoint®—and tells more lies in a table depicting the “Number of Doses” obtainable from vials using different syringes:

Number Of Doses								
Vial Size (ml)	Total Vial Volume <sup>3</sup> (ml)	Assumed Dose Size (ml)	BD Integra™ 3ml Syringe vs. BD™ Conventional 3ml Syringe			BD Integra™ 3ml Syringe vs. Brand A Retracting 3ml Syringe		
			BD Integra™ 3ml Syringe (Avg. Waste Space = 0.026ml)	BD™ Conventional 3ml Syringe (Avg. Waste Space = 0.092ml)	Number of Additional Doses with BD Integra <sup>4</sup>	BD Integra™ 3ml Syringe (Avg. Waste Space = 0.026ml)	Brand A Retracting 3ml Syringe (Avg. Waste Space = 0.185ml)	Number of Additional Doses with BD Integra <sup>4</sup>
0.5	0.6	0.25	2.17	1.75	1	2.17	1.38	1
1.0	1.1	0.25	3.99	3.22	0	3.99	2.53	1
		0.50	2.09	1.86	1	2.09	1.61	1
2.0	2.15	0.25	7.79	6.29	1	7.79	4.94	3
		0.50	4.09	3.63	1	4.09	3.14	1
5.0	5.3	0.25	19.20	15.50	4	19.20	12.18	7
		0.50	10.08	8.95	2	10.08	7.74	3
		1.00	5.17	4.85	1	5.17	4.47	1
10.0	10.5	0.25	38.04	30.70	8	38.04	24.14	14
		0.50	19.96	17.74	2	19.96	15.33	4
		1.00	10.23	9.62	1	10.23	8.86	2
20.0	20.6	0.25	74.64	60.23	14	74.64	47.36	27
		0.50	39.16	34.80	5	39.16	30.07	9
		1.00	20.08	18.86	2	20.08	17.38	3
30.0	30.8	0.25	111.59	90.06	21	111.59	70.80	41
		0.50	58.56	52.03	6	58.56	44.96	14
		1.00	30.02	28.21	2	30.02	25.99	5
50.0	51.0	0.25	184.78	149.12	35	184.78	117.24	67
		0.50	96.96	86.15	10	96.96	74.45	22
		1.00	49.71	46.70	3	49.71	43.04	6

125. According to the table’s footnotes, the difference between the BD Integra dose column and the Brand A dose column gives the data in the corresponding “Number of Additional Doses with BD Integra” column. Running the math indicates that the table presents hypothetical results based on BD assumptions about dead space and overfill. As the saying goes: “Garbage in; garbage out.” Calculations that use false dead space data produce false results.








126. Although the table actually presents a hypothetical, BD’s discussion of the table begins with the words, “The tests results confirm . . . ,” thus creating the false impression that the table presents the results of actual tests. In fact, the table’s data is so mathematically-tuned to BD’s assumptions that it cannot be based on real-world tests—not unless BD ran its tests using

superhuman clinicians with calibrated eyeballs and superfine-tuned, eye-hand coordination, capable of drawing super-exact doses, and using medication vials in which the overfill is precisely limited to the standard minimum. In fact, nurses are human and imprecise, and real-world vials are routinely overfilled beyond the USP-recommended standard. Few nurses draw medication with anywhere near the precision implied by the table, and even fewer medications require such precision. In fact, BD does not have “test results” that “confirm” the data presented in the table.<sup>4</sup>

127. The Low Waste Space White Paper is still published by BD on the web, cited in BD press releases,<sup>5</sup> distributed by its salesmen to consumers, and submitted with contract bids. Upon information and belief, the Low Waste Space White Paper was submitted to the U.S. government in a successful bid for Integra sales at least as recently as 2008.

128. Another series of pdf-formatted documents linked at the Literature Ordering Info page is the Brochures / In-Servicing Materials links:

**Brochures/In-Servicing Materials:**

- [BD Integra™ Next Generation Low Waste Space Brochure](#) 
- [BD Integra™ Syringe 1ml Brochure](#) 
- [BD Integra™ Syringe 3ml Brochure](#) 
- [BD Integra™ Syringe 1ml In-service Poster](#) 
- [BD Integra™ Syringe 3ml In-service Poster](#) 
- [BD Integra™ 3ml Syringe Customer Points to Practice](#) 
- [Quick Reference: Usage Tips](#) 
- View a Video on the BD Integra™ Syringe  
[Windows Media® Player](#)

<sup>4</sup> The data presented in this table and similar BD advertising also encourages “pooling” excess medicine from many vials to create extra doses—a practice discouraged by the CDC because it increases the risk of cross-contamination and infection.

<sup>5</sup> See, e.g., [http://phx.corporate-ir.net/phoenix.zhtml?c=64106&p=irol-newsArticle\\_print&ID=477321&highlight=](http://phx.corporate-ir.net/phoenix.zhtml?c=64106&p=irol-newsArticle_print&ID=477321&highlight=)

129. The first link is to the “Next Generation Low Waste Space Brochure”<sup>6</sup> which, in addition to false claims on other topics, repeats data from the Low Waste Space White Paper, and encourages the dangerous practice of pooling medication.

130. The second link is to the BD Integra™ Syringe 1 mL Brochure<sup>7</sup> which, in context with the other materials, touts the false claim that BD has an advantage in delivering a more accurate dose than others. The brochure makes other false claims which will be discussed later.

131. The third link is to the BD Integra™ Syringe 3 mL Brochure.<sup>8</sup> In addition to other false claims explored elsewhere in this Complaint, the BD Integra™ Syringe 3 mL Brochure contains the following words and chart with false “Brand A Retracting Syringe” claims similar to those described above:

Low waste space means reduced medication waste and medication costs for a healthcare facility. The example below illustrates the variation in cost and number of doses obtained from a multi-dose vial when using a BD Integra™ Syringe, BD Conventional Syringe or Brand A Retracting Syringe.

HEPATITIS B CHART			
SYRINGE TYPE	DRUG	# OF DOSES PER VIAL	COST PER DOSE
BD Integra™ Syringe	Hepatitis B	3.18	\$65.94
BD Conventional Syringe	Hepatitis B	3.00	\$69.82
Brand A Retracting Syringe	Hepatitis B	2.70	\$77.57

***The BD Integra™ Syringe provides a medication cost savings!***

Example:  
 $\$69.82 - \$65.94 = \$3.88$  (a dose) x 1000 (doses) = **\$3,880.**

132. Again, the detail suggests that BD has hard data to establish these claims, presumably referring to competing syringes actually available to consumers. Yet, during substantially all of the time that BD has been publishing this brochure on the web and through its other advertising and promotions, Retractable’s VanishPoint® has been the only other retracting

<sup>6</sup> [http://www.bd.com/safety/pdfs/BD\\_Integra\\_Syringe\\_Next\\_Generation\\_Low\\_Waste\\_Space\\_0575.pdf](http://www.bd.com/safety/pdfs/BD_Integra_Syringe_Next_Generation_Low_Waste_Space_0575.pdf)

<sup>7</sup> [http://www.bd.com/safety/pdfs/BD\\_Integra\\_1mL\\_Syringe\\_brochure\\_0507.pdf](http://www.bd.com/safety/pdfs/BD_Integra_1mL_Syringe_brochure_0507.pdf)

<sup>8</sup> [http://www.bd.com/safety/pdfs/BD\\_integra\\_ordering\\_info2.pdf](http://www.bd.com/safety/pdfs/BD_integra_ordering_info2.pdf)

syringe on the market. BD has no data to support its “Brand A” claims as to VanishPoint®—or as to any other retracting syringe in commercial use (if there are any).

133. Because of BD’s size, longevity, and reputation, its misrepresentations are accepted as fact and relied on by consumers, including the U.S. and various state governments, and also adopted and re-published by authorities, who are influential with other consumers.

134. For example, the following state authorities re-publish the BD Integra™ Syringe 3 mL Brochure, with its false “Brand A Retracting Syringe” claims, on their web sites: the Oregon Department of Human Services,<sup>9</sup> the New Mexico Department of Health,<sup>10</sup> and the Michigan Department of Community Health.<sup>11</sup>

135. As a further example, the Journal of the American Medical Association published an article in 2005 that cites to the Low Waste Space White Paper. In that article, which is available on the web, the author not only cites to the white paper but also provides the internet address that effectively puts that false advertising at the web-equipped reader’s finger-tips.<sup>12</sup>

136. The above examples are illustrative only and do not exhaust the instances of BD’s false and misleading advertising concerning dead space, dose accuracy and medication savings. In its “online resource” and updates to it, and in other advertising and promotion to customers after July 2, 2004, BD has made and continues to make false and misleading statements of fact and direct comparisons concerning BD syringes and Retractable’s VanishPoint® syringes. The launch of BD’s “online resource” was timed to coincide with the flu season, and BD’s false

---

<sup>9</sup> <http://www.oregon.gov/DHS/ph/imm/docs/H1N1Ancillary.pdf>

<sup>10</sup> [http://www.health.state.nm.us/H1N1/documents/BD\\_Integra\\_Syringe\\_102609.pdf](http://www.health.state.nm.us/H1N1/documents/BD_Integra_Syringe_102609.pdf)

<sup>11</sup> [http://Michigan.gov/documents/mdch/BD\\_Integra\\_Syringe\\_102609\\_298776\\_7.pdf](http://Michigan.gov/documents/mdch/BD_Integra_Syringe_102609_298776_7.pdf)

<sup>12</sup> Cosgrove, et al., “Strategies for Use of a Limited Influenza Vaccine Supply,” JAMA, Jan. 12, 2005—Vol. 293, No. 2, pp. 229-232 (see n. 11, citing “Becton, Dickinson and Company Web site. BD Integra. 3ms Syringe [white paper]. Available at [http://www.bd.com/safety/pdfs/Low\\_Waste\\_Space\\_whitepaper\\_0554.pdf](http://www.bd.com/safety/pdfs/Low_Waste_Space_whitepaper_0554.pdf). Accessed November 11, 2004.”). The article is re-published at <http://www.hopkins-cepar.org/sns/resources/edhsu1.pdf>.

claims concerning dead space, dose accuracy and medication savings continue to be an effective and favorite theme of BD's during flu season—a critical time for syringe sales.

137. In addition to its “online resource,” BD regularly makes false claims about dead space, dose accuracy, and medication savings in other advertising and promotion, including, but not limited to, its contract bids, in-service training, sales presentations, and other contacts with distributors, Group Purchasing Organizations (“GPOs”), regional buying groups and collectives, large hospital systems, U.S. and state governments, and other purchasers. Similar false claims are scripted for use by BD sales representatives in their contacts with customers.

138. On the simplest level, BD overstates Retractable's dead space by three times its actual amount; however, there are additional subtleties to BD's lies and misleading omissions.

139. First, designed dead space and actual, in-use dead space may differ. For example, whether syringes are sold with detachable needles or with permanently-attached needles has an effect on actual, in-use dead space. The vast majority of BD syringe products are sold as separate needles and syringes that the user must tighten or assemble prior to use. The actual, in-use dead space of syringes with detachable needles may be higher than the designed dead space because of variations in how tightly the user screws the two pieces together.

140. BD knows that two-piece designs may have both increased and variable dead space. Indeed, BD press releases and advertising concerning its Integra 1 mL syringe, one of the few BD products sold only with a permanently-attached needle, cite its “integral” needle design as a basis for reduced dead space. Retractable's VanishPoint® syringes come only with permanently-attached, i.e., “integral” needles.

141. Conversely, BD offers most sizes of its conventional, Safety-Lok, SafetyGlide, Eclipse and 3 mL Integra products as two-piece syringe and needle assemblies. BD's two-piece

designs introduce human error and human non-error variability into what is, in effect, the final assembly-step—which is for the healthcare worker to screw the two pieces together. Different clinicians, with their varying grip strengths, distractions, and operational pressures, may screw the pieces together more or less tightly. As a result, dead space of BD syringes in actual use may vary substantially from the designed dead space, from use to use, and from user to user.

142. BD's advertising about dead space misrepresents and fails to account for or mention the impact of this variable. BD's testing, if any, does not account for—or intentionally eliminates—variations in real-use dead space of its two-piece designs.

143. BD syringes with removable needles also suffer from needle pop-off in which the needle comes off the end of the syringe during injection or post-injection activation of the safety feature. Needle pop-off sometimes involves the needle simply falling off the syringe; however, because of the high forces created in injection, there are reports involving BD's products—especially Integra—in which the needle flies across the room upon pop-off. Any time it occurs, needle pop-off presents a safety hazard. If it occurs before or during injection, it negatively impacts dead space, medication savings, and dose accuracy.

144. As a result of their two-piece design, BD syringes suffer from needle pop-off; Retractable's VanishPoint® syringes do not. Needle pop-off is a particularly frequent problem for BD's SafetyGlide, Eclipse, and Integra. While touting its detachable needles, none of BD's advertising accounts for or mentions BD's needle pop-off problems. *See, e.g.* the About BD Integra page discussed above.<sup>13</sup> Upon information and belief, BD test data supposedly supporting its advertising about dead space, dose accuracy, and medication savings fails to account for needle pop-off.

---

<sup>13</sup> <http://www.bd.com/hypodermic/products/integra/>

145. Needle pop-off also creates an increased risk of contaminated needle-stick injury. The needle may hit the nurse's lap, leg or foot as it falls or get lost in the bed sheets, where it presents a lurking hazard for housekeeping personnel. Retrieving it also increases the risk of injury. Needle pop-off may also spread contaminated fluids on hospital surfaces—another route of disease transmission. BD's advertising and promotion ignores these increased risks.

146. BD has also had significant problems with its Integra syringe malfunctioning and, in particular and most prominently as it relates to dead space, dose accuracy and medication savings, with leakage and premature plunger rod collapse of the Integra 3 mL syringe.

147. Leakage refers to medication or vaccine moving into syringe assemblies or outside the syringe instead of through the needle and into the patient. Injection pressure commonly forces medicine into the screws of the detachable needle assembly on the Integra and sometimes right outside the syringe. Leakage negatively affects both dead space and dose accuracy. Because clinicians are sometimes forced to re-administer injections in order to insure that patients receive a full dose, leakage also effects vaccine and medication savings.

148. Premature plunger rod collapse refers to a recurring problem with the Integra 3 mL syringe in which the cutter-portion of its two-piece plunger advances prematurely and cuts the seal at the front of the plunger, allowing medicine to flood the hollow plunger and preventing further administration of medicine. When premature plunger rod collapse occurs, dose accuracy becomes guess-work, and the actual, in-use dead space of the Integra soars.

149. When the plunger collapses early the Integra patient certainly does not receive a strictly accurate dose; however, more importantly, collapse may come so early that the patient does not receive a sufficient and effective dose. Thus, in addition to its impact on BD's canards

about dead space, dose accuracy, and medication savings, Integra's premature plunger rod collapse problem imperils public health.

150. The Integra plunger must collapse in order to retract the needle, but BD puts the onus on the clinician to notice that collapse has occurred too early—and to calculate what that means for the patient. As though to hide the problem, BD makes the Integra plunger opaque so the clinician may not notice that medicine has moved into the plunger instead of the patient. And, in the case of a premature plunger rod collapse, the structure and opacity of the device makes guess work of determining how much medicine has made it into the patient.

151. BD's advertising and promotion fails to account for these prominent and recurring problems with Integra. And, upon information and belief, BD test data supposedly supporting its advertising concerning dead space, dose accuracy, and medication savings also fails to account for leakage and premature plunger rod collapse.

152. BD also promotes needle-changing. This is the practice of assembling a needle and syringe, filling the syringe, discarding the needle used to fill the syringe, and then putting on a fresh needle for injecting the patient. In general, needle-changing has no significant clinical advantages, is wasteful, is dangerous,<sup>14</sup> and benefits only BD's bottom line, because it allows BD to sell two needles with every syringe. Because medication is lost in the first discarded needle and then lost again as dead space when the second needle is attached and the injection administered, needle-changing negatively impacts both dose accuracy and dead space.

153. Although BD promotes needle-changing, dose accuracy, and dead space in the same breath, it ignores, misrepresents or otherwise fails to account for the impact of needle-

---

<sup>14</sup> Compared to injection with a fixed-needle syringe, needle-changing increases the risk of infection by (1) opening a closed, sterile system to environmental contamination and (2) increasing manipulation of the needle and syringe.

changing on dose accuracy and dead space.<sup>15</sup> Upon information and belief, BD test data concerning dead space, dose accuracy, and medication savings likewise fails to account for needle-changing.

154. BD's advertised dead space for its own products is false because it fails to account for these variables inherent in the design of its syringes and their promoted methods of use; however, even setting aside these real-use issues with its syringes and assuming that dead space only refers to design dead space, BD's commercial advertising and promotions concerning dead space, dose accuracy, and medication savings are false and misleading.

155. As noted, the dead space of Retractable's VanishPoint® 3 mL syringe is less than that of BD's conventional, Safety-Lok, SafetyGlide, and Eclipse syringes and far less than depicted in BD's advertising and promotions. BD deliberately misrepresents these facts.

156. Specifically, in its interstate commercial advertising and promotions, BD has made false and misleading statements of fact about the dead space in Retractable's syringes and BD's syringes, including, without limit, at least the following: (1) that BD's conventional, Safety-Lok, SafetyGlide, and Eclipse syringes have less dead space than the VanishPoint® syringe; (2) that the dead space on a VanishPoint® 3 mL syringe is 0.185 mL (three times its actual dead space); (3) that, because of its dead space, VanishPoint® will not draw the full number of doses from a multi-dose vial, e.g., that a clinician using VanishPoint® will be able to obtain only 2.7 doses from a three-dose vial or nine doses from a ten-dose vial; (4) that use of VanishPoint® will leave hospitals critically short of flu vaccine; (5) that cost savings on medicines will or can be achieved by using BD's conventional, Safety-Lok, SafetyGlide, and

---

<sup>15</sup> See, e.g., <http://www.bd.com/hypodermic/products/integra/> (the About BD Integra page) and the rest of the Integra Links described above.

Eclipse syringes instead of VanishPoint®; (6) the dollar amount of or degree of cost savings which might be achieved by using Integra instead of VanishPoint®; (7) the number of additional doses obtainable from a vial, if any, when using Integra; (8) the number of additional vials, if any, that hospitals would supposedly have to buy when using VanishPoint® as opposed to BD's conventional, Safety-Lok, SafetyGlide, Eclipse, and Integra syringes for a given number of doses using a given size of vial; (9) that Integra's waste space volume is 86% lower than Retractable's; and (10) that BD has tests establishing its dead space, dose accuracy, and medication saving claims. These false and misleading claims are made through many interstate channels, including without limit, print advertising, promotional presentations to GPOs, hospital administrators, acute and alternate care facilities, and individual nurses, and internet advertising and promotional materials.<sup>16</sup>

157. BD's false and misleading dead space advertising is egregious and deliberately false, intended to deceive customers, has tarnished Retractable's reputation and good will, cost Retractable customers and sales, and resulted in increased sales of BD syringes during the flu seasons of 2005 and 2006 and in every year after July 2, 2004.

158. **In-patient activation / harm to patient.** BD attacks Retractable's VanishPoint® syringes by falsely claiming or implying that activating the retraction feature on the VanishPoint® while the needle is still in the patient harms the patient.

159. In fact, engaging the retraction feature of the VanishPoint® before removing the needle from the patient causes no harm to the patient. Most importantly, in-patient activation is

---

<sup>16</sup> See, for example and without limitation, the following web materials:  
[www.bd.com/hypodermic/products/integra/wastespace\\_impacts.asp](http://www.bd.com/hypodermic/products/integra/wastespace_impacts.asp)  
[www.bd.com/hypodermic/products/integra/medication\\_savings.asp](http://www.bd.com/hypodermic/products/integra/medication_savings.asp)  
[www.bd.com/hypodermic/products/integra/cost\\_calculator.asp](http://www.bd.com/hypodermic/products/integra/cost_calculator.asp)  
[www.bd.com/safety/pdfs/Low\\_Waste\\_Space\\_whitepaper\\_0554.pdf](http://www.bd.com/safety/pdfs/Low_Waste_Space_whitepaper_0554.pdf)

the key to clinician safety because it effectively eliminates contaminated needle-tip exposure time, that is, the critical period after the contaminated needle is removed from the patient and before it is secured so that it no longer presents a risk of accidental needle-stick injury.

160. BD understands that eliminating this critical exposure period increases safety. Nevertheless, in order to protect and increase its market share, BD continues its false attacks on in-patient activation of retraction technology, and encourages clinicians to remove the needle from the patient before retracting the needle—thus, defeating the primary safety feature of an auto-retracting syringe. One more example of how BD places sales above safety.

161. For example, BD sales personnel tell distributors and other customers that, unless they are very careful, in-patient activation will result in advancing the needle deeper into the patient—a claim which is false or misleading as to the VanishPoint® syringe for several reasons. First, the same action used to inject the medication, e.g., gently squeezing the thumb and forefingers together, easily and automatically initiates retraction of the VanishPoint® needle as delivery of the medication is completed. Thus, there is no reason, need or impulse for the clinician to “lean in” or advance the entire syringe and needle deeper into the patient during retraction any more than while injecting the medicine. Second, the VanishPoint® design prevents the needle itself from advancing relative to the syringe. Third, activation is easy, rapid, and mechanically and directionally precise so that the needle comes out of the patient with no more trauma than a conventional syringe.

162. Nevertheless, through their sales calls, in-service trainings, presentations, and other modes and media, BD sales personnel state or imply to customers that in-patient activation may harm patients, and BD backs this campaign up with print, video, internet and other publications that play on the theme.

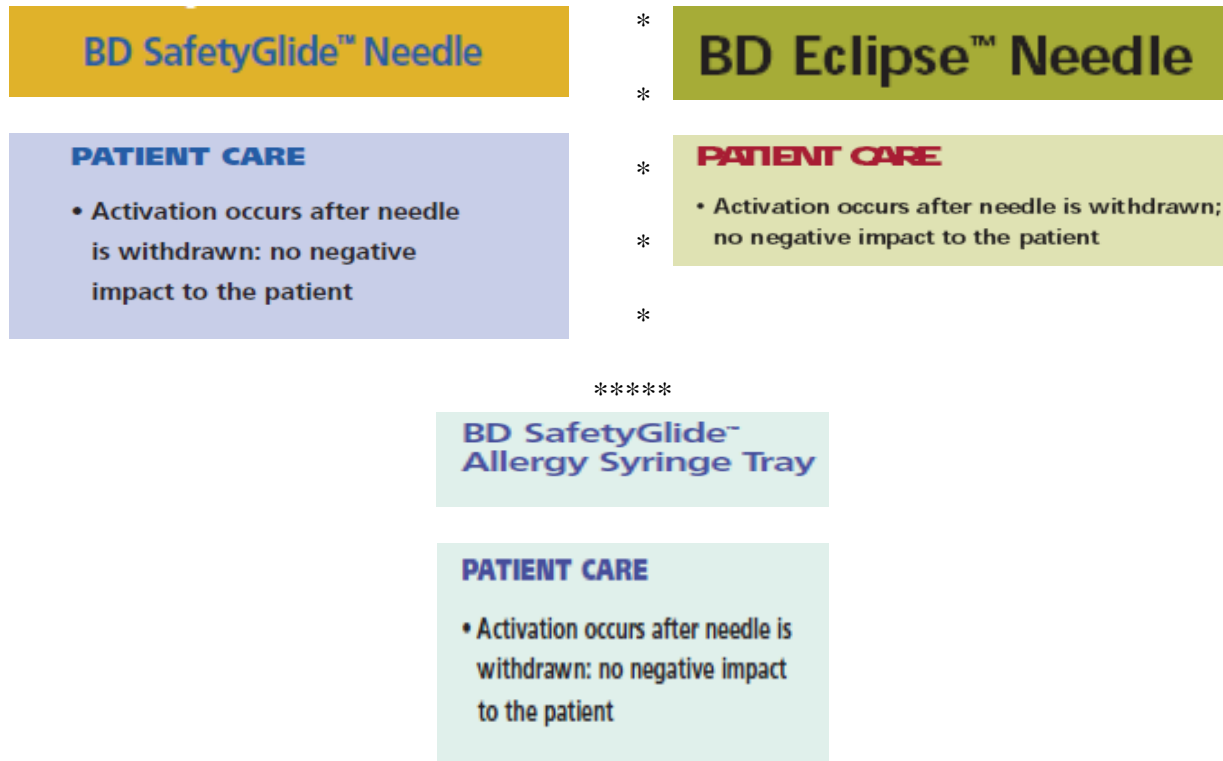
163. When confronted with customers interested in the VanishPoint®, BD sales personnel are taught to ask if the customer ever administers injections to children and to then point out that out-of-patient activation of the VanishPoint® may splatter medication. The implication being that, if they administer injections to children, the clinicians will necessarily want to activate retraction outside of the child. Why? Because according to BD, in-patient activation will either startle or physically harm the child. False claims both—but easily imagined to be true given the general hysteria with which many children confront a hypodermic needle. In fact, that hysteria favors in-patient retraction since the danger of an accidental needle stick soars when the patient is resisting, squirming, or prone to sudden movements, and, therefore, the speed with which the dirty needle is covered becomes that much more critical.

164. BD print and web advertising plays on this tactic of casting doubt on in-patient activation. For example, BD advertises or otherwise promotes its SafetyGlide and Eclipse with this and similar language: “Activation occurs after needle is withdrawn: no negative impact to the patient.”<sup>17</sup> Taken in its market context, such advertising is false and misleading because it falsely states or implies that retractable syringes, in which activation occurs before the needle is withdrawn, do have a negative impact on the patient. That representation is false as to the VanishPoint®.

---

<sup>17</sup> See, e.g.,  
[http://www.bd.com/injection/products/pdf/BD\\_safetyglide\\_needle\\_brochure.pdf](http://www.bd.com/injection/products/pdf/BD_safetyglide_needle_brochure.pdf)  
[http://www.bd.com/injection/products/pdf/BD\\_eclipse\\_brochure.pdf](http://www.bd.com/injection/products/pdf/BD_eclipse_brochure.pdf)  
[http://www.bd.com/allergy/pdfs/allergy\\_syringe\\_brochure\\_0482.pdf](http://www.bd.com/allergy/pdfs/allergy_syringe_brochure_0482.pdf)

165. Exemplars of this false advertising appear in these and similar forms:



166. Likewise, BD advertises and promotes its Integra syringe with this and similar claims: “The BD Integra™ Syringe . . . provides the clinician with the added benefit of choosing when to activate the device, either before or after the needle is withdrawn from the patient.”<sup>18</sup> Such advertising is false, misleading, and dangerous, because it states or implies that activating retraction outside the patient is an “added benefit” for a safety syringe, when, in fact, outside activation increases needle-tip exposure time, thus, reducing safety. Here is an example:

The BD Integra™ Syringe also provides the clinician with the added benefit of choosing when to activate the device, either before or after the needle is withdrawn from the patient. Whatever the clinician's decision, the patient receives the complete medication dose.

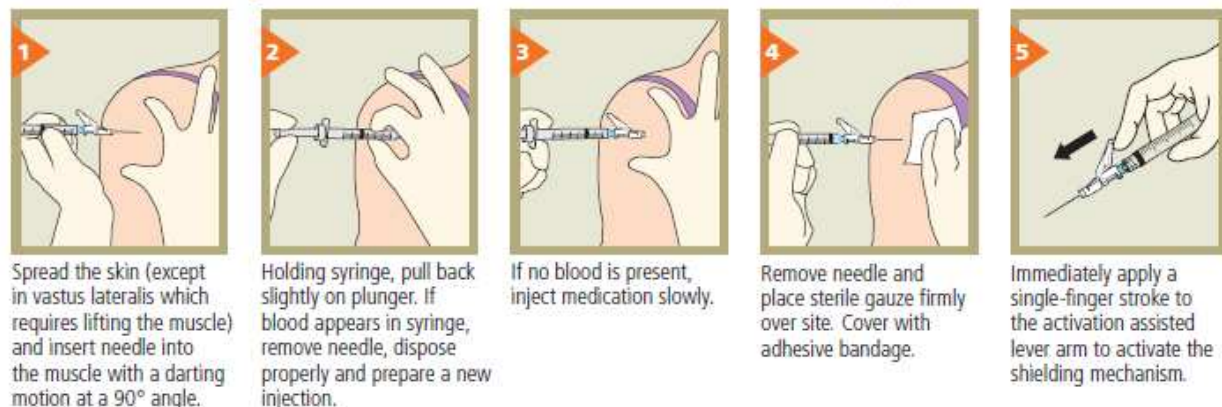
<sup>18</sup> E.g., [www.bd.com/safety/pdfs/BD\\_Integra\\_Syringe\\_Next\\_Generation\\_Low\\_Waste\\_Space\\_0575.pdf](http://www.bd.com/safety/pdfs/BD_Integra_Syringe_Next_Generation_Low_Waste_Space_0575.pdf)

167. In the context of BD's other advertising and promotion, it states or implies that in-patient activation of retraction harms patients. During most of the time that BD has made these claims, VanishPoint® was the only non-BD retracting syringe on the market or generally known in the market. In that context, such advertising and promotion falsely states or implies that in-patient activation of the VanishPoint® safety feature harms the patient.

168. BD's misrepresentations about in-patient activation are egregious, deliberately false, and misleading, intended to, and did, deceive customers. Upon information and belief, in every year after July 2004, they have cost Retractable customers and sales, tarnished Retractable's reputation and good will, and resulted in increased sales of BD syringes.

169. One of the dangers inherent in out-of-patient "safety" mechanisms is plainly—if inadvertently—depicted in BD brochures depicting the steps for use of the BD SafetyGlide and Eclipse syringes.<sup>19</sup> Consider these SafetyGlide instructions:<sup>20</sup>

### Standard Injection Administration and Disposal



Note that even in the perfectly controlled environment of a BD artistic rendering, the fourth step brings the nurse's free hand into the danger zone in front of the just-removed dirty needle as she

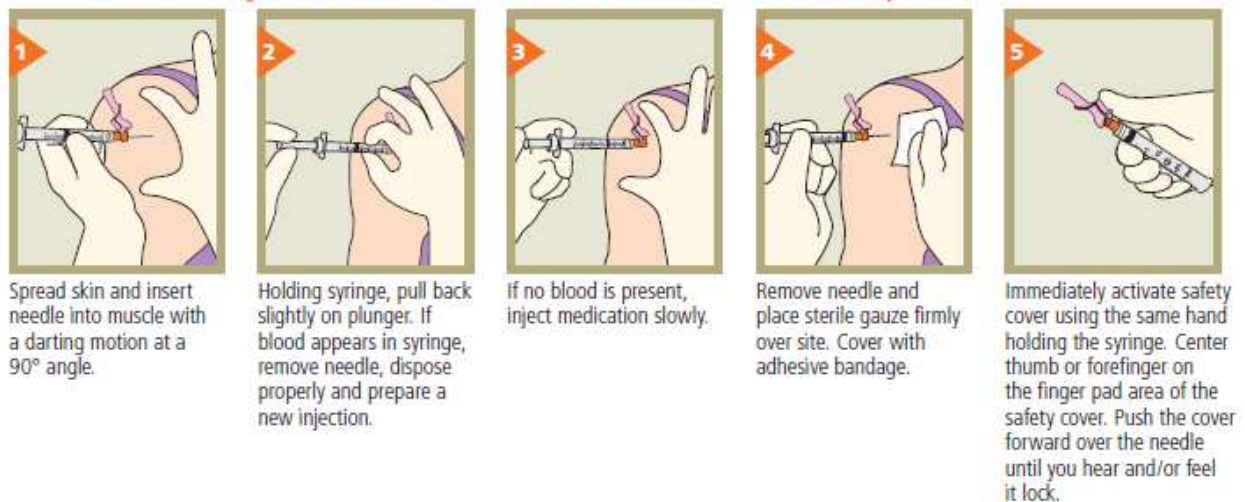
<sup>19</sup> See, e.g., <http://www.bd.com/resource.aspx?IDX=11920> and <http://www.bd.com/resource.aspx?IDX=11917>

<sup>20</sup> <http://www.bd.com/resource.aspx?IDX=11920>

tends to the injection site. And, although BD claims one-handed operation of the SafetyGlide, no explanation is given for how the injecting hand got from the injection position, shown in the third step, to the position required to engage the safety feature, shown in the fifth step. Indeed, this particular user has moved the syringe and dirty needle from her left hand to her right hand before engaging the shielding mechanism.

170. BD's Eclipse instructions<sup>21</sup> show the same safety problems :

### Standard Injection Administration and Disposal



That is, the instructions show how a nurse using the Eclipse brings her free hand into danger in front of a dirty needle when she follows her training and impulses to immediately tend to the patient after removing the needle. And they fail to show how to manipulate the using hand from the injection position to that required to engage the “safety cover” without passing the dirty needle from hand to hand or otherwise bringing the second hand toward the dirty needle.

<sup>21</sup> <http://www.bd.com/resource.aspx?IDX=11917>

171. As these instructions also show and as is discussed below, it is misleading with regard to the real-world use environment to describe the SafetyGlide and Eclipse as one-handed or single-handed safety mechanisms. Yet BD does.

172. **Ease of use and single-handed activation.** Ease of use is important because clinicians tend not to use safety features that make their jobs more difficult. Further, if a clinician has to choose, even for a moment, between safety and caring for the patient, her instinct is to care for the patient. Devices that force this choice on the clinician are less safe for it.

173. True single-handed activation is a desirable feature for a safety syringe, because (1) it makes the safety feature easy to use; (2) any time the clinician uses her second hand to engage the safety feature or to move her first hand into position to do so, the additional time, gross movement, direction of movement, and increased proximity of the second hand to the needle involved in two-handed operation all translate into an increased risk of injury; (3) devices that require two-handed operation often require that the dirty needle be exposed, i.e., removed from the patient, before the safety feature is engaged; and (4) two-handed operation forces the clinician to choose for a moment between dealing with the safe operation of the syringe and dealing with the patient.

174. The safety preference for single-handed operation is recognized by Centers for Disease Control, OSHA, human-factors / needle-safety experts, sharps safety organizations, and BD itself, and it informs the basis for BD's attempts to develop single-handed safety activation.

175. BD's hired experts in litigation have admitted that any time the second hand is brought toward a contaminated needle the risk of accidental needle-stick injury goes up. Indeed, in marketing its products that supposedly feature single-handed activation, BD admits that products that require two hands to activate increase the risk of a needle stick.

176. BD's Safety-Lok requires two-handed activation, which BD admits; nevertheless, BD calls it a "safety" syringe and sells it as such under the name, "Safety-Lok."

177. BD claims single-handed activation for its SafetyGlide, Eclipse, and Integra products; however, they are so difficult to activate with one hand that claiming—without qualification—that the devices feature one-handed activation is false and misleading.

178. A high percentage of nurses do not practice single-handed activation of the shields on the SafetyGlide and Eclipse because single-handed operation of these devices is unreasonably difficult, time-consuming, and distracting in real-world use. In fact, it is common knowledge—and BD knows—that many nurses do not use the "safety" features on SafetyGlide and Eclipse at all and that some actually remove the "safety" features before use.

179. Nevertheless, BD promotes these devices as "single-handed, needle-based safety devices" featuring "Ease of Use" exemplified by "single-handed activation."<sup>22</sup> Depicting single-handed activation, BD touts Eclipse as "Safety made simple" and SafetyGlide as offering "Safety Without Compromise" and "setting the standard in safety" because of "single-handed activation" and "Patented Activation-Assist™ technology for fast and easy needletip shielding."<sup>23</sup>

#### **BD Eclipse™ Needle**

This single-handed, needle-based safety device requires no hard surface for activation, and minimal change in technique.

#### **EASE OF USE**

- Single-handed activation

\*\*\*\*\*

#### **BD SafetyGlide™ Shielding Hypodermic Needle**

BD Activation-Assist™ technology allows for fast and easy, single-handed needle shielding.

#### **EASE OF USE**

- Single-handed activation

<sup>22</sup> See, e.g., [http://www.bd.com/ca/pdfs/safety/products/injection/syringes\\_needles/Eclipse\\_Sales\\_Sheet.pdf](http://www.bd.com/ca/pdfs/safety/products/injection/syringes_needles/Eclipse_Sales_Sheet.pdf)  
[http://www.bd.com/injection/products/pdf/BD\\_safetyglide\\_needle\\_brochure.pdf](http://www.bd.com/injection/products/pdf/BD_safetyglide_needle_brochure.pdf)  
<http://catalog.BD.com/ecat/help/f12/safetywithoutcompromise.pdf>

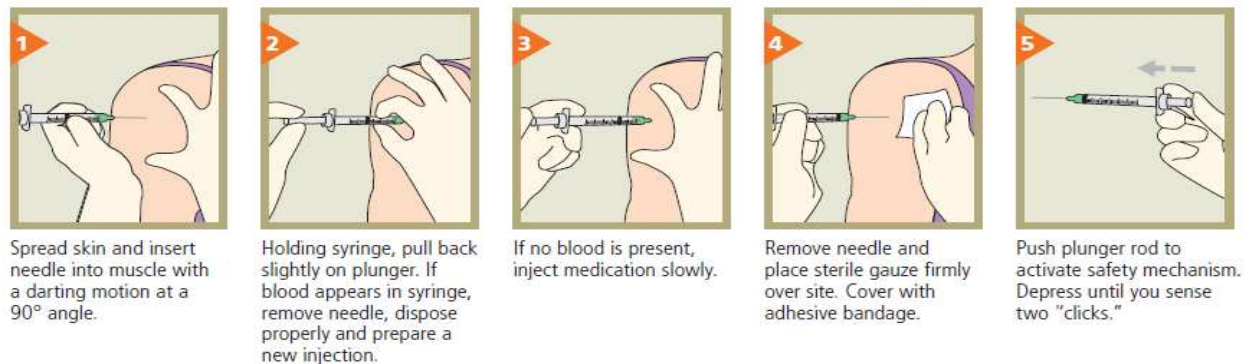
<sup>23</sup> See, e.g., *id.*

180. Again, because of BD's size, longevity, and reputation, its misrepresentations are accepted as fact and relied on by consumers and also adopted and re-published by authorities, who may themselves be consumers and are influential with other consumers. For example, the Oregon Department of Human Services<sup>24</sup> and the New Mexico Department of Health<sup>25</sup> re-publish on their web sites BD brochures with false and misleading claims about the "ease of use" and "single-handed activation" of Eclipse and/or SafetyGlide.

181. Although its design may allow for true single-handed activation by a strong nurse, the BD Integra as manufactured has an unacceptably high activation force which makes it difficult or impossible for those with less grip strength to activate the syringe with one hand. As a consequence, a substantial percentage of users activate the Integra with two-hands.

182. Other users can activate the device with one hand but only if they first remove the needle from the patient—thus, exposing a dirty needle and defeating the primary safety advantage of retraction. In fact, as shown in these instructions from a BD web brochure,<sup>26</sup> BD encourages users to remove the needle before activation—despite its negative impact on safety:

### Standard Injection Administration and Disposal



<sup>24</sup> <http://oregon.gov/DHS/ph/imm/docs/H1N1AncillaryBDSafetyGlide.pdf>

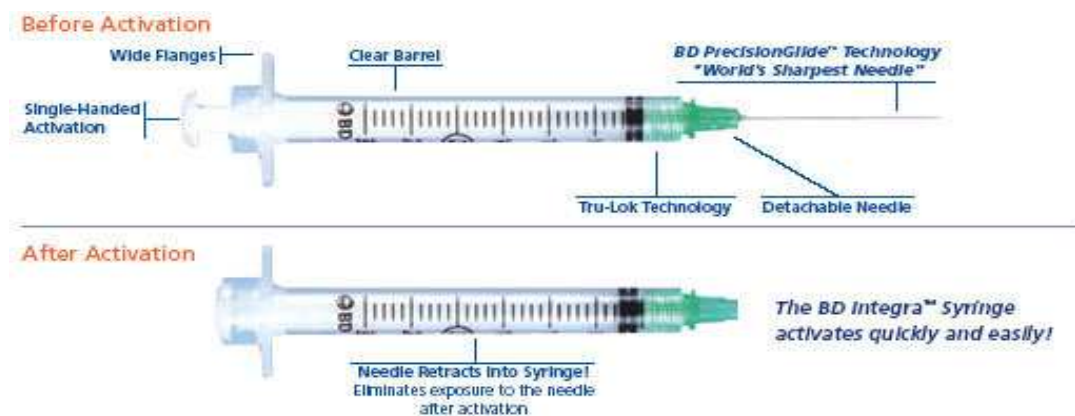
<sup>25</sup> [http://www.health.state.nm.us/h1n1/documents/BD\\_Eclipse\\_Needles\\_102609.pdf](http://www.health.state.nm.us/h1n1/documents/BD_Eclipse_Needles_102609.pdf) and [http://www.health.state.nm.us/h1n1/documents/BD\\_SafetyGlide\\_Needle.pdf](http://www.health.state.nm.us/h1n1/documents/BD_SafetyGlide_Needle.pdf)

<sup>26</sup> <http://www.bd.com/resource.aspx?IDX=11918>

Note how the second hand in the fourth step is, once again, put in jeopardy before a dirty needle. In its fifth frame, the instruction also suggests that the entire device moves during retraction—thus, encouraging the unsafe practice of removing the needle from the patient before initiating retraction. The fifth frame also makes no mention of the contaminated fluid splatter that occurs when a syringe is retracted outside the patient. Splatter that hits an open wound or exposed mucosa (eyes, inside of nose, etc.) may lead to direct infection, and splatter that lands on the clinician's clothing, skin, or shoes or on hospital surfaces, such as bed rails, mobile medication carts, or IV stands, may act as a mobile reservoir spreading infection throughout a health facility.

183. Many Integra users both remove the needle from the patient before activating retraction and use two hands, either to steady the Integra or for a two-handed press on the plunger to achieve the high-activation force required by the Integra's poor design.

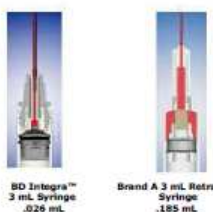
184. BD has known for years that the Integra is unacceptably hard to activate and that many users require two-hands to do it. Yet, as in this example, BD advertising and promotion states that the Integra “activates quickly and easily” and features “single-handed activation”:<sup>27</sup>



<sup>27</sup> See e.g., [http://www.bd.com/safety/pdfs/BD\\_Integra\\_Syringe\\_Next\\_Generation\\_Low\\_Waste\\_Space\\_0575.pdf](http://www.bd.com/safety/pdfs/BD_Integra_Syringe_Next_Generation_Low_Waste_Space_0575.pdf) and [http://www.bd.com/hypodermic/products/integra/attributes\\_3mL.asp](http://www.bd.com/hypodermic/products/integra/attributes_3mL.asp).

185. On the 3 mL Attributes page,<sup>28</sup> the claim that Integra “activates quickly and easily” appears in context with the above-described “Brand A” drawing of the VanishPoint®, thus, suggesting that Integra “activates quickly and easily” as compared to VanishPoint®, the only other retracting syringe on the market:

Compare BD Integra™ 3mL Syringe's .026 mL of waste space volume to BRAND A 3 mL retracting syringe which has .185 mL of waste space volume. Over time, syringe designs with high waste space volume may adversely impact a healthcare facility's bottom line.



BD Integra™ Syringe waste space volume is **86%** lower than Brand A Retracting Syringe.

View product video:  
[Windows Media® Player](#)

BD Integra™ 3 mL Syringe .026 mL

Brand A 3 mL Retracting Syringe .185 mL

The BD Integra™ Syringe design *minimizes* the waste space area to *maximize* the number of doses a clinician is able to aspirate from a multi-dose vial. View the [medication savings](#) experienced with BD Integra™ Syringes.

**Detachable Needle\***

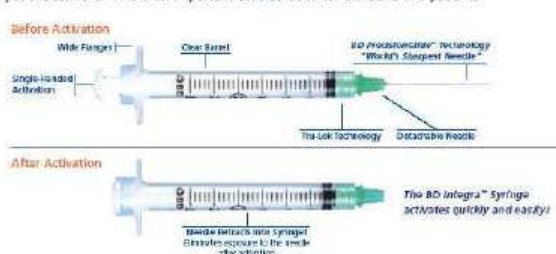
It's the only spring-based 3 mL retracting syringe on the market with a detachable needle. Detachable needle offers clinical flexibility, allowing clinicians to change needles for aspiration and administration.

**Dosing Accuracy\***

The BD Integra™ 3 mL Syringes deliver the complete medication dose, whether the user activates the device before or after the needle is withdrawn from the patient.

**World's "Sharpest" Needle\***

For years, clinicians have relied on the BD PrecisionGlide™ Needle for its ability to maintain its sharpness and promote patient comfort. This is an important consideration for clinicians and patients.



In fact, Integra takes twice the force to activate as, and activates more slowly than, VanishPoint, especially since BD instructs users to remove Integra from the patient before activating.

186. **Safe, safety, and safety-engineered.** BD's Safety-Lok, SafetyGlide, and Eclipse products are no safer than, and can be more dangerous than, conventional needle products. Contaminated needle-stick injuries have actually been known to go up when these non-retracting

<sup>28</sup> [http://www.bd.com/hypodermic/products/integra/attributes\\_3mL.asp](http://www.bd.com/hypodermic/products/integra/attributes_3mL.asp)

BD “safety” devices are introduced into hospitals—a telling fact since clinicians get in-service training, at that time, on the use and purpose of the devices and, thus, are more than usually focused on safety and avoiding needle sticks.

187. One study at a large hospital system showed needle-stick injuries declining only after a test group stopped using the Safety-Lok syringe and returned to conventional syringes. Another study showed a significant increase in needle sticks upon adoption of the SafetyGlide. For years, BD has known of these studies and of the same phenomena with its Eclipse.

188. Still another study by an independent hospital found that needle-stick injuries increased when the hospital began to use BD’s alleged “safety” products in 2003. The same study showed that needle-stick injuries were virtually eliminated when the hospital switched to VanishPoint<sup>®</sup> products in 2004 and 2005. BD knows of this study, too.

189. Public records show that most current so-called “safety” needles sold, most of which are the BD Safety-Lok, SafetyGlide, and Eclipse needles described above, are ineffective. For example, in 2004 the State of Texas received reports of 370 needlestick incidents involving so-called “safety engineered” products. In 243 of those incidents, the alleged “safety mechanism” had not even been activated ([www.state.tx.us/idcu/health/bloodborne\\_pathogens/report/](http://www.state.tx.us/idcu/health/bloodborne_pathogens/report/)– Tables 18 and 19).

190. BD has long been aware that a high percentage of clinicians do not use the “safety” features on the Safety-Lok, SafetyGlide, and Eclipse and that some clinicians actually remove the “safety” features from these devices before use. Accordingly, BD’s Safety-Lok, SafetyGlide, and Eclipse products are dangerous for the additional reason that the alleged “safety” features on those products impede use and are feared or not trusted by, and thus routinely disabled or not activated by, the healthcare workers they are supposed to protect.

191. Despite all of the above, BD continues to advertise the Safety-Lok, SafetyGlide, and Eclipse products as “safe,” “safety,” or “safety-engineered” products.

192. BD falsely represents to consumers that the “safety” features or mechanisms of its Safety-Lok, SafetyGlide, and Eclipse syringes effectively or significantly reduce the risk of an exposure incident and that BD has studies proving reduced exposure risk resulting from these features. BD also falsely represents that each of these devices are equally safe and/or equally effective in reducing exposure risk and that studies support this claim as well.

193. BD has long known (and used to publicly state) the simple fact that the critical time for contaminated needlestick injuries occurs after injection or blood-drawing and before the contaminated needle is covered so that it cannot stick the user or bystander. If one can *eliminate* that exposure window, that needle-tip exposure time, then one can eliminate most contaminated needlestick injuries.

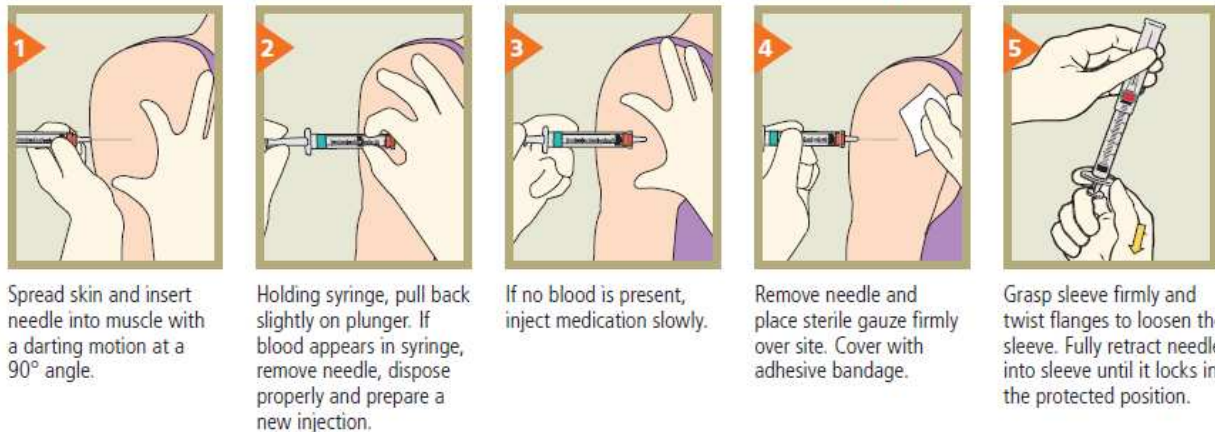
194. By design, Retractable’s VanishPoint® syringes eliminate that critical exposure period because the needle retracts from the patient directly into a shielded position. In effect, the contaminated needle tip is never exposed; therefore, VanishPoint® practically eliminates accidental contaminated needlestick injuries.

195. By design, BD’s Safety-Lok, SafetyGlide, and Eclipse cannot eliminate that critical exposure period because their needle covers are manually moved into place after the needle is removed from the patient—as shown in the SafetyGlide and Eclipse instructions depicted above and in the Safety-Lok instructions depicted below:<sup>29</sup>

---

<sup>29</sup> <http://www.bd.com/resource.aspx?IDX=11921>

## Standard Injection Administration and Disposal



Because they do not eliminate contaminated needle-tip exposure time, Safety-Lok, SafetyGlide, and Eclipse cannot eliminate contaminated accidental needle-stick injuries. Nor can they reduce needle-stick injuries or exposure to blood-borne pathogens to the lowest feasible extent or even to a meaningful extent.

196. Nevertheless, in its advertising, promotion, and other marketing, viewed in their full context, BD directly states or implies that use of the Safety-Lok, SafetyGlide, and Eclipse will “prevent percutaneous injuries,” are “effective in eliminating or minimizing occupational exposures” to blood-borne pathogens, and are “effective in reducing occupational exposures to the lowest feasible extent” (emphasis added).<sup>30</sup>

### What are engineering controls?

The term “engineering controls” is now defined and means controls that isolate or remove the BBP hazard from the workplace. They are described as “safer medical devices used to prevent percutaneous injuries ...

\*\*\*

### What do I have to do to be in compliance?

- Update or create a BBP Exposure Control Plan.
- Evaluate and implement “safer medical devices” where they are found to be effective in eliminating or minimizing occupational exposures. Frontline healthcare workers are to be part of the evaluation and selection process.

\*\*\*

<sup>30</sup> See, e.g., <http://www.bd.com/safety/faqs/> (BD Resource Center, “Needlestick Safety and Prevention Law Frequently Asked Questions & Answers”) (accessed and printed on 7/29/2007 and again on 4/16/2010).

**Are there any "loopholes" or exceptions to the use of "safer medical devices"?**

There is no list of exceptions. Employers must review and consider commercially available devices to determine whether they are effective in reducing occupational exposures to the lowest feasible extent.

Because their design forces the user to pull the dirty needle from the patient before manually covering it, BD's two-handed devices cannot eliminate or reduce needle sticks to the "lowest feasible extent." Only a retracting syringe can.

197. In some instances, BD falsely claims to have "data on file" that establishes its safety claims. Here is one example of such a false establishment claim:

BD (Becton, Dickinson and Company) offers a broad portfolio of products to help improve patient outcomes and healthcare worker safety. This includes the widest array of safety-engineered devices available anywhere. No matter where clinicians work, it's important to protect healthcare workers from accidental sharps injuries by using safety-engineered devices whenever possible. BD provides a full line of products with excellent clinical performance for injection, infusion, blood collection, surgical incision, sharps disposal and much more. These products have been designed to meet the strict requirements of OSHA-regulated facilities and to help achieve a safer work environment.\*

\* Data on file at BD.

Having correctly stated that the OSHA mandates devices that are "effective in reducing occupational exposures to the lowest feasible extent," BD implies that one can meet that standard "no matter which BD safety injection you choose."<sup>31</sup>

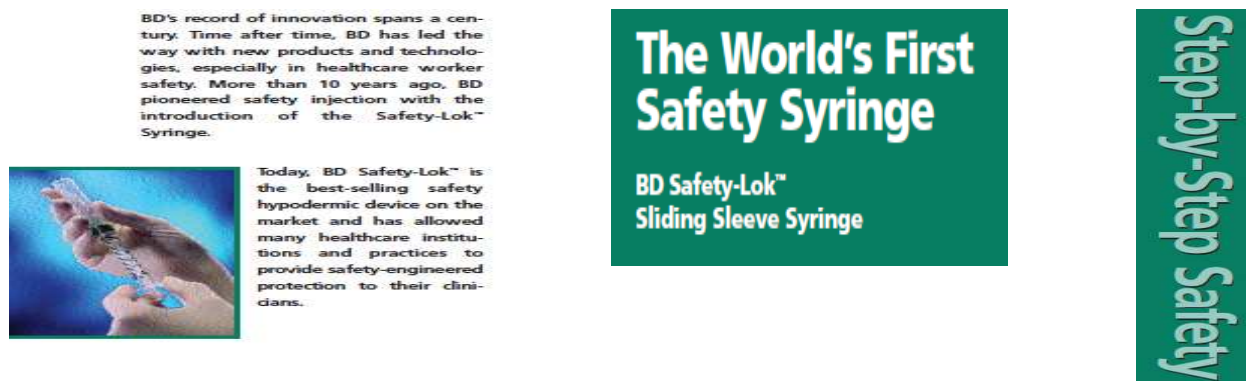
---

<sup>31</sup> The BD brochure, "The BD Family of Safety Injection Products," marked "© 2006" was still available on the web at [mcguffmedical.com/pdf\\_main.aspx?file=Safety\\_Family\\_Alternate\\_Site.pdf](http://mcguffmedical.com/pdf_main.aspx?file=Safety_Family_Alternate_Site.pdf) at least as late as April 2010.

Today, as federal regulations mandate that safety devices be implemented in both acute-care and alternate-site facilities, BD renews its commitment to healthcare workers by offering the widest array of safety-engineered devices available anywhere. And no matter which BD safety injection product you choose, you're always assured that each aspect has been designed specifically with the clinician—and the patient—in mind.

198. BD's Safety-Lok is no safer, and indeed can be more dangerous, than a conventional syringe. In fact, it is merely a conventional syringe with an add-on outer sleeve that a user must grasp with his second hand and slide the length of the barrel to cover the exposed needle after an injection. Those actions move the second hand toward the dirty needle, increasing risk of injury. BD nevertheless uses the words, terms, and names "safe," "safety," "safety-engineered" and similar descriptions in commercial advertising and promotion to describe the nature, characteristics, and qualities of the Safety-Lok syringe, all in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

199. For example, BD advertises the "BD Safety-Lok™ Sliding Sleeve Syringe" as offering "Step-by-Step Safety" and as "The World's First Safety Syringe." Boasting that "BD Safety-Lok is the best-selling safety hypodermic device on the market," BD claims that Safety-Lok offers "safety injection" and will "provide safety-engineered protection."<sup>32</sup> BD has made these and similar claims in interstate advertising after July 2, 2004 to the present.



<sup>32</sup> See, e.g., [http://www.bd.com/injection/products/pdf/BD\\_safetylok\\_syringe\\_brochure.pdf](http://www.bd.com/injection/products/pdf/BD_safetylok_syringe_brochure.pdf) (accessed July 2007).

200. BD's SafetyGlide is no safer, and indeed can be more dangerous, than a conventional syringe. In fact, the SafetyGlide is a conventional syringe with a small, straight slider or a bulky, hinged-lever slider, attached to the base of the needle, that, when pressed by the user, extends to cover the needle. Consequently, after withdrawing the needle from the patient, the user must (1) reach toward the needle to engage the lever or slider and then (2) push it over the needle. Both actions take time and dexterity and place the user's hand and/or finger(s) in close proximity to the blood-contaminated needle, thereby increasing the risk of a needlestick injury. Even when a nurse uses only one hand, it is not uncommon to "miss" the slider or for the slider to jam such that her finger slips off the slider directly onto the needle tip. Nevertheless, BD uses such false and misleading phrases as "Single-handed immediate activation"<sup>33</sup> and "Safety . . . Finger stays behind the needle at all times"<sup>34</sup> in its SafetyGlide advertising.

201. Design flaws in the SafetyGlide also result in needle pop-off, that is, when the user attempts to engage the "safety" feature, the contaminated needle and needle assembly may literally fall off the syringe and stick users or get lost in the bed sheets only to later stick unwitting laundry personnel. Even if the fallen needle is recovered, the additional handling and disposal of it presents further opportunities for injury.

202. Moreover, the SafetyGlide shield is flimsy, does not cover the entire needle, and is easily removed. When activated as directed, SafetyGlide may also splatter contaminated fluids on surrounding room surfaces or personnel. BD nevertheless uses the words, terms, and names "safe," "safety," "safety-engineered," and similar descriptions in commercial advertising

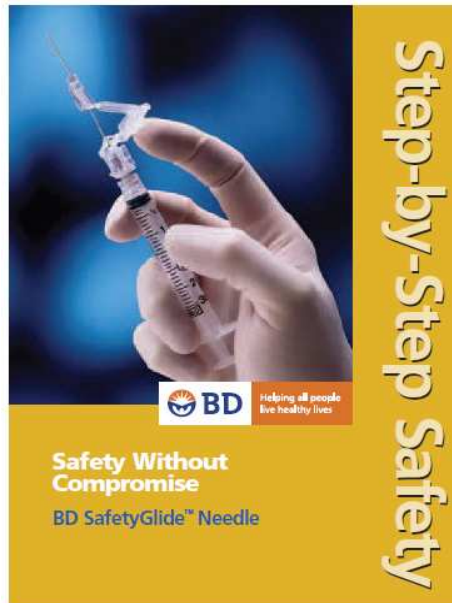
---

<sup>33</sup> See, e.g., <http://www.bd.com/pharmaceuticals/products/safety-engineered.asp>

<sup>34</sup> See, e.g., [http://www.bd.com/allergy/pdfs/allergy\\_syringe\\_brochure\\_0482.pdf](http://www.bd.com/allergy/pdfs/allergy_syringe_brochure_0482.pdf)

and promotion to describe the nature, characteristics, and qualities of the SafetyGlide syringe, all in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

203. For example, in interstate advertising after July 2, 2004 and to the present day, BD has advertised its SafetyGlide as offering “Safety Without Compromise” and “Step-by-Step Safety”<sup>35</sup> and claims that “SafetyGlide is setting a new standard in safety injection.”<sup>36</sup>



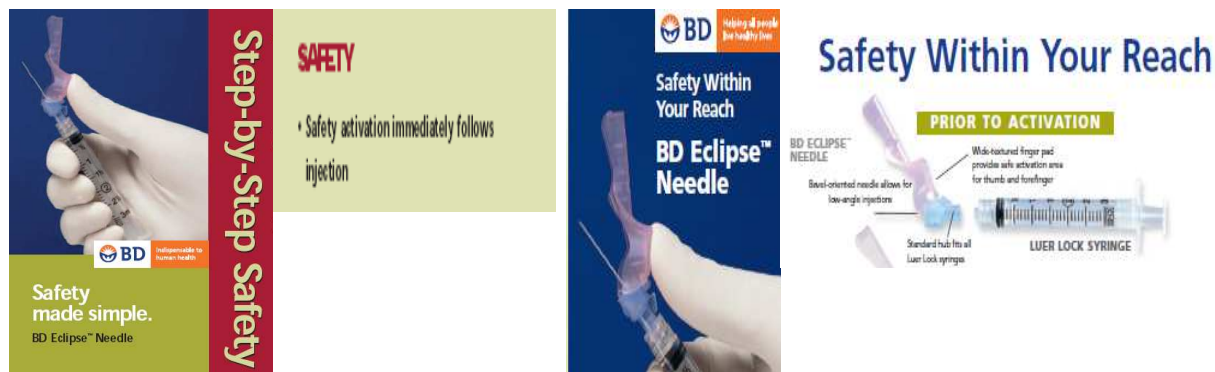
204. Like SafetyGlide, BD’s Eclipse products are no safer, and indeed can be more dangerous, than conventional products because they include a hinged shield at the base of the needle that when hit or pushed flips into place over the needle. A user must, after injecting a patient and withdrawing the needle from the patient, reach toward the needle to flip the shield into place, or else move the syringe, with its exposed, blood-contaminated needle, to a table-top or other firm surface against which the hinged shield can be flipped into place. Flipping the shield into place sometimes throws blood and/or aerosolized fluids from the needle and onto healthcare providers, patients, or surrounding surfaces, thus, increasing the risks of infection.

<sup>35</sup> See, e.g., [http://www.bd.com/injection/products/pdf/BD\\_safetyglide\\_needle\\_brochure.pdf](http://www.bd.com/injection/products/pdf/BD_safetyglide_needle_brochure.pdf) (accessed July 2007).

<sup>36</sup> See, e.g., [http://www.bd.com/injections/products/pdf/BD\\_safetylok\\_syringe\\_brochure.pdf](http://www.bd.com/injections/products/pdf/BD_safetylok_syringe_brochure.pdf) (accessed July 2007).

205. Eclipse's design flaws may result in needle pop-off when the user attempts to engage the "safety" feature, that is, the dirty needle falls off the syringe and sticks the user or gets lost in the bed sheets only to later stick unwitting laundry personnel. The Eclipse shield is flimsy, does not cover the entire needle, and is easily removed, often intentionally and sometimes accidentally. BD nevertheless uses the words, terms, and names "safe," "safety," "safety-engineered" and similar descriptions in commercial advertising and promotion to describe the nature, characteristics, and qualities of the Eclipse syringe, all in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

206. For example, BD claims Eclipse "Puts Safety Within Your Reach" and provides "safe activation area," "safety activation," "Step-by-Step Safety" and "Safety made simple."<sup>37</sup> BD advertised these and similar false or misleading claims after July 2, 2004 to the present.



207. Much of BD's advertising and other marketing also fails to disclose the material splatter risk of the Eclipse.<sup>38</sup> BD clearly understands the importance of that risk, since it has, in

<sup>37</sup> See, e.g., [http://www.bd.com/injection/products/pdf/BD\\_eclipse\\_brochure.pdf](http://www.bd.com/injection/products/pdf/BD_eclipse_brochure.pdf) and [http://www.bd.com/hypodermic/pdf/BD\\_Eclipse\\_Brochure.pdf](http://www.bd.com/hypodermic/pdf/BD_Eclipse_Brochure.pdf)

<sup>38</sup> See *id.*

the past, warned of splatter risk for both SafetyGlide and Eclipse, and currently touts “Virtually no splatter upon activation” as a “SAFETY” feature of the SafetyGlide.<sup>39</sup>



208. BD continues to create new advertisements touting Safety-Lok, SafetyGlide, and Eclipse as “safety-engineered devices” and “safety injection products.”<sup>40</sup>



209. “Why can’t it be zero? It can.” Despite the inherent danger of its non-retracting “safety” syringes, BD has claimed interstate use of, and filed for U.S. registration of, the mark “Why can’t it be zero?” BD advertising uses this mark pairs that question, “Why can’t

<sup>39</sup> [http://www.bd.com/injection/products/pdf/BD\\_safetyglide\\_needle\\_brochure.pdf](http://www.bd.com/injection/products/pdf/BD_safetyglide_needle_brochure.pdf) (“SAFETY . . . Virtually no splatter upon activation”).

<sup>40</sup> See, e.g., [http://www.bd.com/injection/products/pdf/BD\\_eclipse\\_brochure.pdf](http://www.bd.com/injection/products/pdf/BD_eclipse_brochure.pdf); see also <http://www.bd.com/safety/products/injection/index.asp> (on-line and copyrighted in 2007).

it be zero?,” with this answer, “It can.” Such advertising creates the false and misleading impression that use of BD’s “safety” products will reduce needle sticks to “zero.”

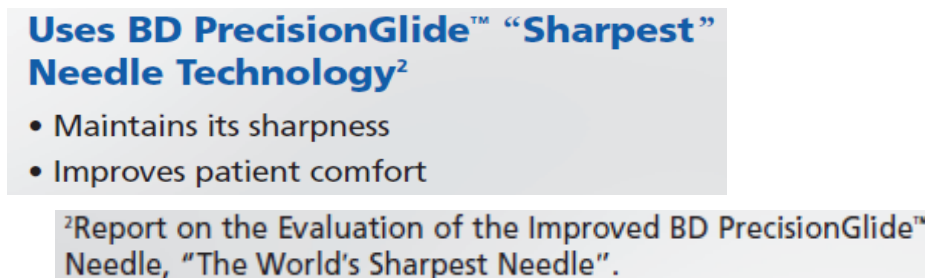
210. All of BD’s false advertising damages both Retractable and the American public, in particular, American healthcare workers. By promoting the Safety-Lok, SafetyGlide, and Eclipse as “safe” when in fact they are not, BD implies to healthcare workers and healthcare employers not only that the products provide protection from needle-stick injuries, but also, and just as damaging, that purchase and use of such products will place the healthcare entity in “compliance” with the provisions of the Needlestick Safety and Prevention Act by eliminating or minimizing exposure to blood borne pathogens. Thus, false advertising allows BD to sell its high-profit-margin, unsafe “safety” products to circumvent the intent of the Needlestick Safety and Prevention Act and block market access of Retractable’s clearly safer technology.

211. **“World’s Sharpest Needle” and Needle Dulling.** In advertising and promotion, BD claims that its hypodermic and blood collection products feature the “World’s Sharpest Needle;” that its needles are sharper than all major competitors’ needles; that sharper needles are always less painful to patients than less sharp needles; and that, as a result, BD needles are less painful to patients than non-BD needles, including VanishPoint®. BD claims that its syringe needles are not dulled by insertion through a medicine stopper and/or maintain sharpness better than competing needles, including VanishPoint®, and are, therefore, more comfortable to patients. BD represents or implies that it has studies establishing all of these claims. These claims are false and misleading, and studies, if any, in BD’s possession do not establish these claims.

212. For example, the BD Integra™ Syringe 3 mL Brochure<sup>41</sup> states that Integra has the “World’s Sharpest Needle” and implies that this increases patient comfort:



213. Another part of the Integra 3 mL Syringe brochure explicitly claims that BD’s “Sharpest” needle “maintains its sharpness” and “improves patient comfort:”



214. Other Integra 3 mL ads state “PrecisionGlide Needle Technology . . . promotes patient comfort,” again citing the 1999 “Report . . .” that it is “The World’s Sharpest Needle:”

**Detachable Needle:**

The BD Integra™ 3ml Syringe is the only retracting syringe with a detachable needle. The clinician now has the option of using different needle sizes for aspirating and administering various medications.

The BD Integra™ 3ml Syringe uses BD PrecisionGlide™ Needle Technology. For years, BD has manufactured the BD PrecisionGlide™ Needle which promotes patient comfort.<sup>3</sup>

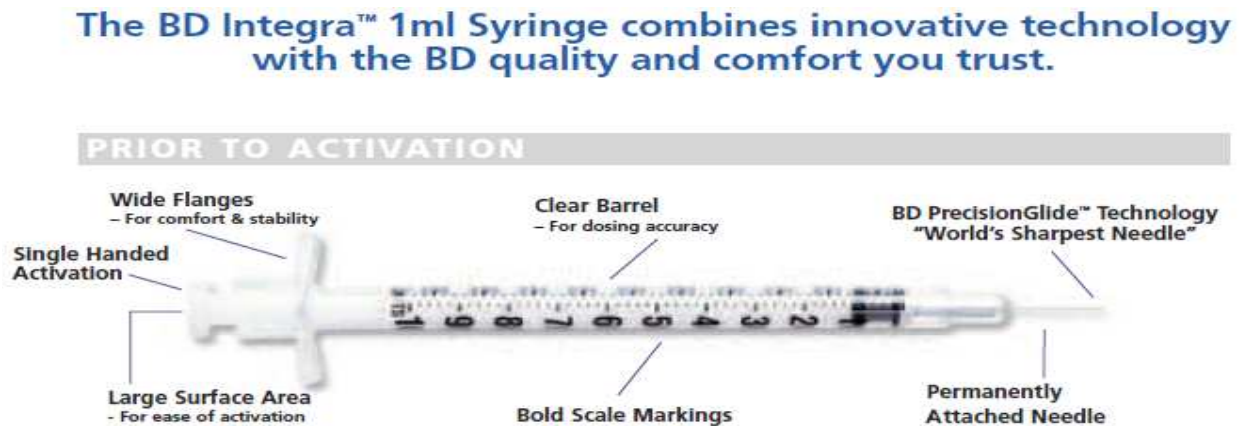


**Detachable Needle**

<sup>3</sup> Report on the Evaluation of the Improved BD PrecisionGlide™ Needle. “The World’s Sharpest Needle” (1/99).

<sup>41</sup> [http://www.bd.com/safety/pdfs/BD\\_integra\\_ordering\\_info2.pdf](http://www.bd.com/safety/pdfs/BD_integra_ordering_info2.pdf)

215. BD makes the same “World’s Sharpest Needle” and comfort claims for its smaller Integra in a brochure from the Integra links, the BD Integra 1 mL Syringe brochure:<sup>42</sup>



216. BD advertises that “Only BD offers all safety syringes with the World’s Sharpest Needle, for enhanced patient comfort,” vowing “All claims are supported by data on file at BD:”

**Only BD** offers all safety syringes with the World’s Sharpest Needle, for enhanced patient comfort.

BD, BD Logo and all other trademarks are property of Becton, Dickinson and Company. ©2008 BD. All claims are supported by data on file at BD.

**Sharp**  
**Only BD** offers the World’s Sharpest Needle to enhance her comfort.

BD, BD Logo and all other trademarks are the property of Becton, Dickinson and Company. ©2006 BD. All claims are supported by data on file at BD.

<sup>42</sup> [http://www.bd.com/safety/pdfs/BD\\_Integra\\_1mL\\_Syringe\\_brochure\\_0507.pdf](http://www.bd.com/safety/pdfs/BD_Integra_1mL_Syringe_brochure_0507.pdf)

217. A 2006 BD catalog, “The BD Family of Safety Injection Products,” sent to distributors and alternate site customers (e.g., out patient clinics) and still published on a California distributor’s web site,<sup>43</sup> identifies Integra, SafetyGlide, Eclipse and Safety-Lok syringes and needles as the “BD Safety Injection Family” and makes these “world’s sharpest” needle claims:

**All members of the  
BD Safety Injection Family  
share these “core” benefits.** . . .

**These benefits include:**

- BD PrecisionGlide™ Needle, the “world’s sharpest,” to promote patient comfort.

218. BD also claims the “World’s Sharpest Needle” in separate advertising for its conventional, Safety-Lok, SafetyGlide and Eclipse needles.<sup>44</sup>

219. In fact, BD needles are no sharper than and frequently test to be less sharp than those on the VanishPoint® and, upon information and belief, other brands. Upon information and belief, BD knows that VanishPoint® needles are sharper than BD’s and that BD’s claims for improved, increased or enhanced patient comfort are equally false vis-à-vis the VanishPoint®.

220. Moreover, BD’s claim to have data on file supporting these false claims is itself false, misleading, damaging and actionable. The “Report on the Evaluation of the Improved BD PrecisionGlide™ Needle, ‘The World’s Sharpest Needle,’” that BD sometimes cites<sup>45</sup> is ten years old and does not support the claims.<sup>46</sup> Upon information and belief, BD has no studies that

<sup>43</sup> [mcguffmedical.com/pdf\\_main.aspx?file=Safety\\_Family\\_Alternate\\_Site.pdf](http://mcguffmedical.com/pdf_main.aspx?file=Safety_Family_Alternate_Site.pdf) (accessed April 7, 2010)

<sup>44</sup> See, e.g., [http://www.bd.com/hypodermic/pdf/BD\\_SafetyLok\\_Brochure.pdf](http://www.bd.com/hypodermic/pdf/BD_SafetyLok_Brochure.pdf) at p. 2 (accessed April 3, 2010 and touting the BD Safety-Lok as having the “World’s Sharpest Needle for greater patient comfort”).

<sup>45</sup> See, e.g., [http://www.bd.com/ca/pdfs/safety/products/injection/syringes\\_needles/Integra\\_Sales\\_Sheet.pdf](http://www.bd.com/ca/pdfs/safety/products/injection/syringes_needles/Integra_Sales_Sheet.pdf)

<sup>46</sup> E.g., [http://www.bd.com/hypodermic/pdf/bd\\_precisionglide\\_needle\\_sharpest\\_needle\\_report.pdf](http://www.bd.com/hypodermic/pdf/bd_precisionglide_needle_sharpest_needle_report.pdf)

truly support—and, in fact, has studies that contradict—its sharpest needle claims.

221. As noted above, these claims are incorporated in BD brochures that have been relied on and re-published by public health authorities, thus perpetuating these lies, bolstering their impact, and making them particularly difficult to counter.<sup>47</sup>

222. BD's sharpest needle claims are also incorporated in oral sales presentations, and BD also claims that competing syringe needles, including VanishPoint®, are dulled by insertion through a medicine stopper to an extent that effects patient comfort, and that clinicians concerned with patient comfort should, therefore, change needles between drawing medication and administering an injection. BD states or implies that it has data establishing these claims. The claims are false, and BD has no studies that establish them.

223. BD's false and misleading advertising and promotion described above is ongoing; longstanding; material; likely to influence and has influenced consumer decisions; difficult to counter in light of its pervasiveness, BD's market dominance, and Retractable's slender customer base; and has injured and is likely to continue to injure Retractable and competition generally. Retractable brings claims for all such injuries accruing after July 2, 2004, and seeks both damages and injunctive relief.

**BD suppresses information about its unsafe “safety” syringes.**

224. To evaluate and select appropriate safer needle devices, consumers need to know which devices work and which do not. In short, they need accurate data—by brand, manufacturer, and model—about which devices are used when needle-stick injuries or other needle-related exposures to blood or body fluids occur. BD knew this when it helped fund

---

<sup>47</sup> E.g. [http://www.health.state.nm.us/H1N1/documents/BD\\_Integra\\_Syringe\\_102609.pdf](http://www.health.state.nm.us/H1N1/documents/BD_Integra_Syringe_102609.pdf)

development of the Exposure Prevention Information Network (“EPINet™”) reporting system which provides for the collection of that data.

225. Back when BD had the only “safety” syringe on the market, EPINet™ was developed by Dr. Janine Jagger and colleagues at the International Healthcare Worker Safety Center (the “Center”) at the University of Virginia. EPINet™ Needlestick & Sharp Object Injury Report forms have a space for the user to report “brand/manufacture” and “model” of the device involved in each injury.<sup>48</sup>

226. Although hundreds of facilities use the EPINet™ forms and data base software offered by the Center, a group of about seventy hospitals actually report their EPINet™ data back to the Center, which publishes a yearly report of that data. The Center reports all of the data except the “brand/manufacture” and “model” of the devices involved in injuries.<sup>49</sup>

227. BD funds the Center and, through its influence, causes the Center to withhold this brand, manufacturer, and model information that would allow large institutional consumers, such as hospital systems, to see which models injure healthcare workers without going through the expensive, annoying, and potentially life-threatening trial and error process of trying a different brand each year until finding one that reduces injuries.

228. Suppression of this information also helps keep buyers from spotting the lies in BD’s marketing and makes it extremely difficult to neutralize or otherwise offset BD’s false advertising and promotion.

---

<sup>48</sup> See <http://www.healthsystem.virginia.edu/internet/epinet/forms/soi2001.pdf> (report form) at items 12a. and 12b.

<sup>49</sup> See <http://www.healthsystem.virginia.edu/internet/epinet/epinetdatareports.cfm> (annual reports).

**BD Engages in Exclusionary Contracting with the Effect of Frustrating the Intent of the Needlestick Prevention Act, Impairing Competition and Eliminating Smaller Competitors**

229. From and after July 2, 2004, BD has employed various forms of exclusionary and otherwise anticompetitive contracts with healthcare facilities in order to frustrate, impair, and substantially foreclose competition from Retractable and all other actual or potential manufacturers of safety syringes and safety IV catheters, sometimes referred to herein as safety needle products. On information and belief, BD's contracts are often multi-year contracts that frequently require the other party to purchase exclusively from BD or to purchase a high percentage of its requirements from BD. Under BD's exclusionary contracts, the prices that healthcare facilities pay for BD's products are conditioned on the purchasers maintaining BD's market share by agreeing to fill all, or nearly all, their safety needle product demand by purchasing BD products to the exclusion of competitive products.

230. Under these exclusionary and otherwise anticompetitive contracts, healthcare providers risk the forfeiture of substantial BD rebates, as a penalty, unless they purchase very high levels of their product needs from BD. Indeed, under BD's contracts, if a healthcare entity were to fall even slightly below BD's target level as the result of purchasing a competitor's safety needle products, the healthcare entity would be penalized by: (a) becoming obligated to pay higher prices for all or most BD products the entity purchases; and (b) losing post-purchase rebates for all or most BD products it purchases. BD's contracts are unreasonable and have no business justification; the purpose and effect of these agreements is to maintain BD's monopoly.

231. BD's exclusionary penalty strategy works by penalizing healthcare entities for purchasing products from BD's competitors. BD's purchase requirements have the purpose and

effect of denying market access to Retractable and other potential and existing competitive manufacturers, thereby foreclosing and excluding them from relevant markets.

232. BD also maintains its market power by unlawful bundling, or conditioning discounted prices or rebates for products on a healthcare entity's commitment to purchase BD products for most, if not all, of the entity's needs in each of various product categories. For example, through BD's bundling practices, a healthcare entity receives discounted prices or rebates for its purchases of several types of BD products, but only if the healthcare entity satisfies BD's requirements by buying a dominant amount of its needs for products in BD's bundle. The healthcare entity only earns rebates or discounts on a particular product if it satisfies the exclusivity, loyalty, market share, or other volume requirements for all the other products in the bundle.

233. Likewise, BD has bundled rebates and discounts on its conventional needles with rebates and discounts on its alleged "safety" needles. Thus, BD has been able to leverage its monopoly power in the markets for conventional needle products to impede and substantially foreclose competition in the relevant market for safety needle products.

234. Similarly, BD bundles rebates for its needle products with unrelated healthcare products. Healthcare entities incur penalties even if they purchase BD products for all of their needs in numerous product categories, but buy even a small amount of a competitor's safety needle products. The prospect of such a penalty creates disincentives that makes it economically impractical or impossible for a healthcare entity to purchase a BD competitor's safety needle products. BD's bundling practices exclude and foreclose competition in markets in which BD has market power and thereby unlawfully maintain BD's market dominance.

235. Many of BD's competitors in the safety needle products market are companies that concentrate in, manufacture, and sell specialized product lines. As a result, BD's penalty programs prevent Retractable and other BD competitors from competing on price for their specialized products because they are unable to offer equal, offsetting discounts or price reductions for those other products since they do not make those products. Even if a BD competitor substantially reduces the price for its safety needle devices, for example, that reduction will not compensate the healthcare entity for the loss of discounts or rebates BD would eliminate for other BD products in order to penalize the healthcare entity for shifting some or all of its safety needle device purchases from BD to the BD competitor. That this is so is proven by the sales program discussed above where Plaintiff dropped its prices dramatically on the VanishPoint<sup>®</sup> syringes but sales to the acute care market remained flat. BD's practices reward healthcare purchasers for purchasing BD's safety needle devices, in lieu of any other manufacturer's safety needle devices, not because BD's safety needle devices are of higher quality or are less expensive (which they are not), but in order to retain greater discounts or concessions on products the other manufacturers do not produce.

236. To make up for the bundled rebates the healthcare entity would relinquish if it purchased the Retractable safety syringes, Retractable would have to give its safety syringes away, or in some cases, pay the healthcare entity to take them because the combined rebates on all of the products in BD's bundle is likely to be greater than the entire price of the safety syringes made by Retractable. No producer of safety needle devices that was as equally or more efficient as BD and that produced products of equal quality would be able to compete with BD's bundled rebates unless it had as broad an array of products as BD.

237. Likewise, upon information and belief, BD's bundled rebates, as described above, are exclusionary because after the full amount of BD's rebates given on all bundled products are allocated to the safety needle devices, BD's resulting price is below its production cost for its safety needle devices. This is certainly the case if the rebates are allocated to the Integra retracting syringes that BD introduced specifically to stop wide spread adoption of the VanishPoint<sup>®</sup> syringe and to monopolize the safety needle market. The rebates and discounts employed by BD have the potential to exclude a hypothetical equally efficient producer of the competitive products.

238. In 2005 BD decided to price its Integra 3 cc retracting syringe product line at or near cost of production to be sure to freeze out the VanishPoint<sup>®</sup>. BD also planned to simply give away 1 cc Integra products in order to be sure and capture what it saw as a growing market for retractable syringes. BD could do this because even if the rebates and discounts it provided through its exclusionary contracts made the Integra line itself unprofitable, the profits on its other products and so-called safety syringes would lessen or eliminate those losses while the Integra kept the VanishPoint<sup>®</sup> off the market. In this way BD could impede Retractable (and any other would-be supplier of safety syringe products) from gaining the efficiencies of volume necessary to survive and compete.

239. BD's anticompetitive contracts are held in strict confidence by BD and BD requires its healthcare customers to keep the contracts confidential. Upon information and belief, if a healthcare customer were to disclose the terms of its BD contract to Retractable, the customer would risk a lawsuit for breach of contract or misuse of trade secrets. Furthermore, the healthcare entity would be threatened with the loss of rebates on all of BD's bundled products. As a result, Retractable has not seen all of the contracts nor the specific terms of all of the

contracts. Retractable believes that BD's contracts contain additional anticompetitive terms that restrain competition other than those alleged in this Second Amended Complaint.

240. Even though some of these contracts do not impose an absolute obligation to meet market shares or minimum purchase requirements, conditioning the amount of discounts or rebates or side payments on achieving those levels is an effective foreclosure. Anticompetitive effects flow from the foreclosure not from the means used to obtain it. After all, even an absolute contractual obligation to buy from one supplier is at worst a promise to either do so or pay contractual damages. Using loyalty rebates simply sets a different penalty on noncompliance, and one that is far more enforceable. With BD's loyalty rebates BD can unilaterally impose a penalty for noncompliance by just withholding the annual rebate without even going to court.

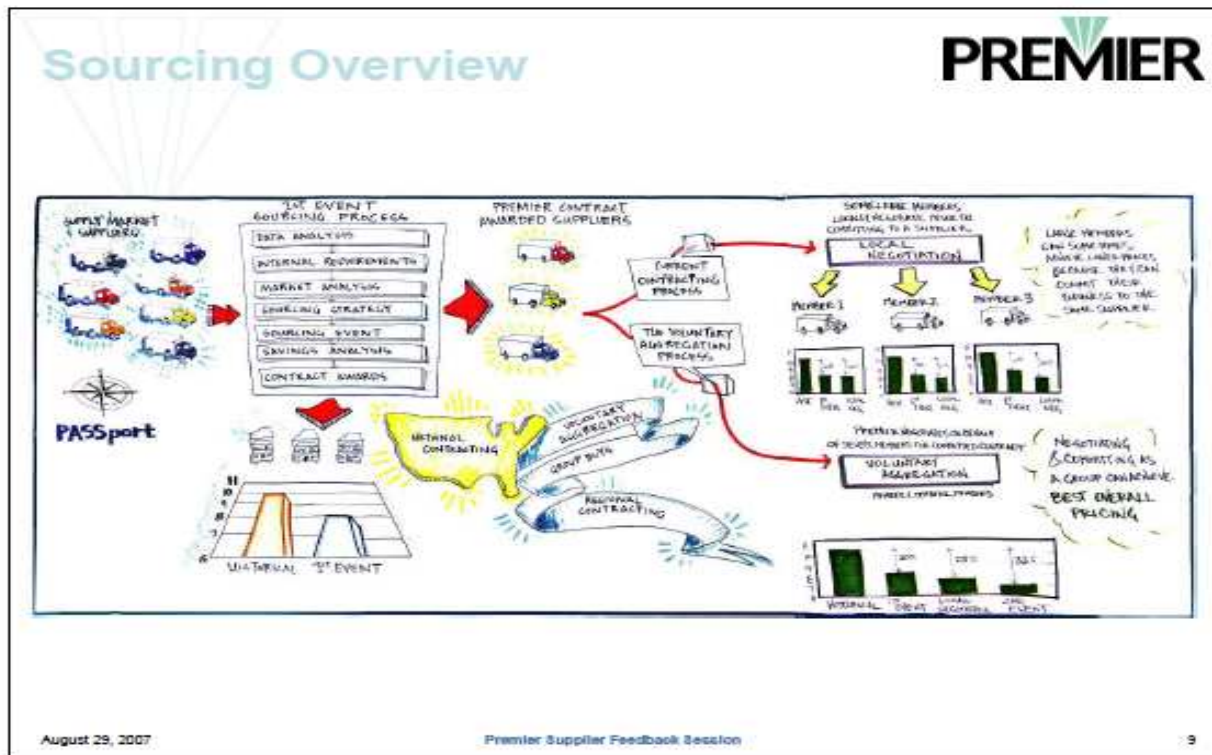
241. The fact that hospitals willingly entered into BD's contracts does not mean they are not exclusionary. Although each buyer receives only a small discount each may do so and agree to the required exclusionary policies to be sure it is not at a disadvantage to its rivals. Because each buyer agrees, they collectively create the ability for BD to maintain its enhanced market power and charge them all higher prices than would otherwise have prevailed in the market. Indeed, where, as here, the buyers (or buyer's agents such as GPOs) are intermediate purchasers they have incentives to agree to preserve or enhance BD's market power (by excluding Retractable and others, or raising their costs) in exchange for side payments that split BD's supracompetitive profits.

242. In addition, 98 percent of American hospitals are members of Group Purchasing Organizations ("GPOs"). GPOs offer most products used by their member hospitals. Hospitals join GPOs through membership contracts that require member hospitals to do most or all of their

purchasing through the GPO. GPOs, in turn, enter into multi-year contracts with manufacturers and suppliers of products used by hospitals. The resulting list of GPO suppliers constitutes the “approved” list for purchases by member hospitals. Upon information and belief, BD has entered into contracts with GPOs, large GPO members, or GPO-assisted regional collaboratives or buying groups, that is, voluntary aggregations of smaller GPO members, that require the GPOs’ member hospitals to purchase high levels of their safety needle devices requirements from BD in order to maintain favorable price discounts. At minimum, BD asks for and receives special treatment from the GPOs in return for sharing with them a portion of its super-competitive profits as side payments, while appearing to comply with the letter of the law.

243. In addition, on information and belief, BD enters into so-called “second tier,” “second event” or “aggregation” contracts directly with hospitals and hospital groups. These are exclusive dealing arrangements that provide for additional “discounts” to hospitals, and unless the hospitals agree to these anti-competitive arrangements, they are penalized by paying higher prices for BD products. GPOs have made driving hospitals to these sole-source “second tier” contracts an explicit feature of the “service” they provide to their member hospitals and clinics.

244. Premier, which claims to be the nation’s largest GPO, has explained the process in a PowerPoint-style presentation, titled “Supplier Feedback Session, August 29, 2007.” Slide 9 of that presentation is particularly revealing:



245. Slide 9 depicts how sole-source contracting has simply been pushed down from the level of national contracts with the GPO to the level of regional and local contracts with the GPO members—all with the assistance of the GPO. Following the diagrammatic flow left to right, Slide 9 first shows seven trucks representing seven potential suppliers for a given product. After a “1st Event Sourcing Process” the seven trucks become three trucks, representing three “Premier Contract Awarded Suppliers.” The GPO can then point to the fact that several suppliers are listed on any given “1st Event” contract and, in essence, say, “XYZ small manufacturer is a supplier under our national contract; therefore, XYZ is not blocked from the market.”

246. However, the process does not stop with a first event contract, but instead continues down one of two paths, each leading to a second event contract in which buyers commit to a single supplier for substantially all purchases of a given commodity.

247. Thus, following the diagrammatic flow across the top of Slide 9, one path leads through the “Current Contracting Process” in which “some large members locally negotiate prior to committing to a [single] supplier.” The visual shows the first event, multi-source contract’s three trucks (representing three suppliers) leading to a second event, single-source contract with one truck (representing one supplier or source) paired with each contracting member.

248. In other words, these “large members” have committed to purchase from a single supplier, and the GPO process has once again led to a sole-source contract. As the call-out in Slide 9 notes “they can commit their business to the same supplier.”

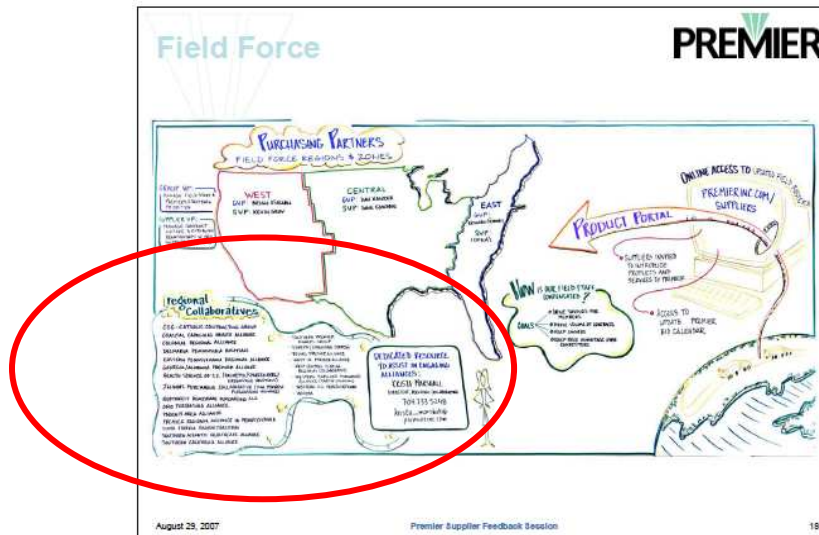
249. A parallel path across Slide 9 shows a slightly different route to sole-source contracts. Through “The Voluntary Aggregation Process,” smaller members band together (depicted as “Voluntary Aggregation, Member 1, Member 2, Member 3”) to negotiate with Premier’s help for a “committed” (i.e., sole-source) contract. As the slide notes, “Premier negotiates on behalf of select members for committed contract.”

250. Throughout these and similar GPO documents, “commit,” “committed contract,” “committing,” “commitment,” “complying,” “compliance” and other like terms are buzz-word synonyms that mean buying substantially all of a particular product or class of products (e.g., syringes) from a single supplier or source (e.g., BD)—thus, blocking competition from other suppliers with innovative, higher quality, or more safe products.

251. In sum, Slide 9 shows the different paths from multi-source GPO contracts to sole-source national, regional or individual contracts, referred to as “second event” or “second

tier” contracting—terms implied<sup>50</sup> by but not used on Slide 9, but which have become industry parlance. BD is a primary participant of this anticompetitive practice in the relevant markets.

252. Some of the large groups of hospitals that have banded together with Premier’s aid to participate in the “voluntary aggregation,” “group buys,” and “regional contracting” discussed in Slide 9 are listed in Slide 18 under the heading “regional collaboratives:”



253. Likewise, MedAssets, another GPO, offers its members the Next Generation SELECT program that: “is a high compliance program that drives savings through standardization of platforms.” Next Generation SELECT requires hospitals to rely on “single supplier sourcing by product category,” to be “compliant with preferred distributors,” and to be “compliant with selected platforms and categories at an 85% or greater level.” BD participates in the Next Generation SELECT program, including its “single supplier sourcing” (i.e., sole-source) and/or compliance requirements. MedAssets reports that it “serves more that 125 health systems, 3,300 hospitals, and 40,000 non-acute care healthcare providers.” *See, e.g.,* <http://ir.medassets.com/releasedetail.cfm?ReleaseID=485606>.

<sup>50</sup> Implied in that an event following next after the “1st event” would be a “second event.”

254. As reported in Modern Healthcare in 2007, in an article titled “Moving Beyond the Hospital,” Premier and MedAssets are not the only GPOs driving individual hospitals and groups to sole-source contracts. A section of the article titled “Compliance, compliance, compliance,” describes how:

. . . GPOs . . . grow business by pushing for greater contract compliance from their member hospitals in the area of medical-surgical supplies purchasing. Many are trying to increase compliance by demonstrating that hospitals can realize greater savings by switching to a sole-source supplier for all purchases of a particular product.

John Strong, . . . CEO of . . . GPO Consorta, says the philosophy of using a sole-source for medical-surgical supplies to drive sales volume and bring members great savings was part of what prompted . . . Consorta to partner with GPO HealthTrust Purchasing Group . . . “Like us, HealthTrust is willing to do sole-source contracting when we see the value in it. We expect 80% compliance from our members” with these contracts.

\*\*\*

Part of the challenge that GPOs face in pushing for greater contract compliance among members is convincing them that giving up the option of purchasing specific products off contract is well worth the savings.

To that end, Todd Ebert, president of . . . Amerinet, says his GPO has invested heavily over the past year in demonstrating the potential savings for hospital clients that comply with purchasing contracts. . . .

Lee Perlman, president of . . . GNYHA Ventures, says his organization embraces a similar philosophy . . .

. . . Perlman says . . . “I think the GPOs that will be successful are those that will hold the hands of their customers and help them understand the value of an individual contract . . . ”

“Moving Beyond the Hospital,” Modern Healthcare, pp. S1-S5 (September 3, 2007).<sup>51</sup> Again, BD is a beneficiary of—and, upon information and belief, a moving force behind—this push to second tier, sole-source contract compliance.

255. Other examples of second event contracting include GPO Novation’s “customized group purchasing model ProvSource” in collaboration with Providence Health System, which resulted in three-year, compliance-driven, exclusionary second event contracts beginning in 2005 with medical-surgical distribution (a category that includes syringes) and quickly yielded 15 new second event agreements. Upon information and belief, as a result of their “commitment” to BD syringes certain hospitals in the Providence Health System have had ongoing problems with needlestick injuries from SafetyGlide and other BD products.

256. Group affiliates of GPOs such as Child Health Corporation of America (CHCA), a group affiliate of Premier Purchasing Partners, Inc., may have their own divisions devoted to second event contracts. For example, CHCA’s Group Purchasing Division works with CHCA’s member hospitals to develop second event contracts with vendors.

257. BD also enters into such exclusionary contracts directly with hospitals, and, upon information and belief, targets distributors with the same type of multi-year, commitment-based, sole-source contracts, designed to suppress competition.

258. BD monitors its sales of a range of products to individual hospitals, regional collaboratives, group affiliates, distributors, and other buyers and penalizes them if they purchase goods, including Retractable’s safety needle devices, that are not part of the contract.

259. Thus, although Retractable has contracts with several large GPOs and is therefore on the approved list of vendors for the GPOs’ hospital members, in reality, purchases of safety

---

<sup>51</sup> See [http://www.novationco.com/pressroom/industry\\_info/modern\\_healthcare\\_survey\\_2007.pdf](http://www.novationco.com/pressroom/industry_info/modern_healthcare_survey_2007.pdf)

needle devices from Retractable would interfere with “compliance” and subject buyers to financial penalties in the forms of reduced “discounts” or rebates from BD, despite the fact that the VanishPoint<sup>®</sup> syringe is the superior product and is priced competitively.

260. The result of BD’s anticompetitive practices is that competition in the safety needle devices markets is artificially suppressed, the cost of products in these markets is inflated, the quality of the products is reduced because the monopolist BD is under no competitive pressure to innovate its products or reduce costs, and healthcare workers are denied the opportunity to use much safer safety needle devices. BD’s anticompetitive acts have substantially decreased competition in the markets for safety needle devices throughout the United States.

261. In addition, these anticompetitive practices frustrate the intent of the Needlestick Prevention Act that healthcare facilities consult with their clinicians on an annual basis to consider and adopt the best possible safety engineered devices for the purpose of eliminating accidental needle-stick injuries or reducing them to the lowest feasible extent.

262. First, BD’s marketing practices make it practically impossible to compare safety needle products based on actual cost of those products. While a “list” price may be available, the bundling, rebating, and discounting practices BD engages in make determination of the actual price of the safety needle products indiscernible.

263. Second, even if a price can be discerned, compliance, commitment, and loyalty programs, “growth” programs and similar schemes that require the customer to continue purchasing BD products in order to obtain the lowest possible cost have the practical effect of chilling any consideration at a yearly meeting to change away from BD products. The annual meetings required by the Needlestick Prevention Act are thus driven by the knowledge that

purchase of any safety needle products other than those offered by BD will drive up costs on a host of other products BD has offered.

264. As an example, BD entered into contracts with hospitals providing incentives based on the amount of dollars spent per bed for a group of products that include conventional hypodermics, flush syringes, Interlink cannula, safety syringes, sharps collectors and pharmacy products. The amount of dollars spent per bed is separately set for individual hospitals to require most if not all their requirements to be purchased from BD and are not generalized volume discounts. The amount of rebate is calculated on the total sales of all products in these categories per bed for a given year. If the dollar amount reaches stated levels the rebate percentage goes up. However, if the dollar amount per bed drops below a certain level the rebates disappear and will not be paid. Qualification for the rebate is based on sales of these groups of products per bed between January 1 and December 31 of the given year. The stated levels are determined based on the hospital's actual prior use to ensure that virtually all sales must be made by BD and are not general volume discounts. As a result, if dollars are spent on safety syringes not sold by BD, the dollars per bed will decline, placing in jeopardy percentage rebates that BD would have paid on all the goods. Thus, instead of considering the cost and safety of safety needle products available to the market as intended by the Needlestick Prevention Act, a committee meeting to consider needlestick safety would recognize that a change to a total safety product such as Plaintiffs' VanishPoint<sup>®</sup> syringes could well result in the loss of significant rebates on the total purchase price of the grouping of products set out in the BD incentive program. Thus, even if Plaintiffs can provide real safety syringe products to the hospital market as efficiently as BD, BD's rebating tied to a bundle of products effectively excludes Plaintiffs from the safety syringe market and tends to destroy competition in those markets altogether.

265. In another version of exclusionary dealing, BD offers multiyear contracts with rebates that are contingent on the hospital ordering at least 90% of the dollar volume of a group of products that it purchased in a designated base year. During the multiyear contract term if the hospital achieves at least a level of 90% of the base year purchases for a group of products rebates will be paid 90 days after the end of the contract year. If the hospital fails to maintain at least the level of 90% of purchases from the base year the contract will terminate and no rebates will be paid.

266. In addition, if the hospital orders more of the group of products than in the base year, substantial rebates are paid back based on the incremental sales. Product groupings for these types of contracts include: conventional needles, conventional syringes, interlink cannula, safety syringes, sharps collectors, flush syringes and pharmacy products. Again, this rebate system is based on bundling and economic incentives to purchasers that effectively exclude consideration of safety needle products, such as produced by Plaintiffs, that will not count toward and can, in fact, cause loss of the substantial rebates from BD based on the sale of the entire bundle of products that BD offers. As a result, Plaintiffs are excluded from the safety needle products markets even though they are able to provide their award-winning total safety retractable syringe products with the same or greater efficiency as BD can offer its inferior shielded syringe product line.

267. Another example of BD's exclusionary conduct is a program where the level of rebates is dependent on the volumes of a bundle of products that are sold in any one year of a multi-year contract. As a prerequisite, the hospital must purchase at least 90% of the volume of a bundle or products as it purchased in the prior year. If that requirement is met, BD pays rebates at increasing levels provided that the hospital meets specified dollar levels of sales for a

group of eligible products. Those eligible products include conventional syringes and needles, Interlink cannula, safety syringes, sharps collectors, flush syringes and pharmacy products. Provided the purchase satisfies the 90% level, the rebates available increase with the total dollar volume for the entire bundle of products. In addition, if the hospital increases its purchases by a stated percentage over its prior year's purchases, BD pays additional rebates, again increasing based on the level of increased purchases. BD pays the rebates only within 90 days after the end of the year for each year of the contract. If the hospital purchases drop below 90% of its prior year purchases on the group of products, the contract terminates and the hospital is not eligible for any rebates. Again, if a hospital offered these terms purchased the safest syringe products from one of BD's competitors, the purchase of the safest syringe products would penalize the hospital by causing it to have to pay more on a whole group of products other than safety syringes. The result is practical exclusion of consideration of any safety needle products other than those offered by BD.

268. In yet another example of exclusionary conduct, BD has conspired with GPOs to provide secret pricing to certain hospital groups that lowers the prices for those groups, to the detriment of other GPO member hospitals who are relying on the same GPO to provide them with the best pricing. These agreements between BD, the GPO and the hospital group provide that BD will sell at the secret reduced prices even after the underlying agreement between the GPO and BD has expired. Thus, while the GPOs appear to offer "multi-source" agreements where smaller rivals can offer their products to the GPO members, in fact, BD makes secret side deals with the GPOs wherein the GPOs provide favored treatment – for example by allowing BD to enter into contracts under the GPO agreement even after it expires. This special and secret treatment is further evidence that BD shares its super-competitive profits with the GPOs as side

payments to reward the GPOs for aiding in BD's maintenance and expansion of its dominant market share.

### **BD Suppresses Healthcare Worker Knowledge of Retractable's Products**

269. Once nurses and hospital medical staff become aware of Retractable's safety syringes, they often demand access to these products. One analyst noted as recently as 2005: "...[E]nd users and distributors are mostly unaware of the retractable-syringe technology." ("Disposable Syringe Markets" p. 11, TriMark Publications, Sept. 2005.)

270. BD's exclusionary contracts that require "compliance" has caused or induced potential customers and trade shows to bar and exclude Retractable's sales staff from entering the premises and demonstrating the advantages of the VanishPoint<sup>®</sup> syringes. For example, Retractable has been barred from one or more trade shows, even though the purpose of the shows was to demonstrate available safety technology to medical staff. Hospital and trade show personnel have tried to justify the exclusion of Retractable's sales personnel by saying their facility is under contract with BD, exclusive to BD, or standardized with BD.

### **BD Controls Market Access Through Exclusive Clubs and Indirect Payments to Hospital Decision Makers**

271. BD's other anticompetitive acts include various schemes for making indirect payments to hospital purchasing executives, chief executive officers, and others within the healthcare industry in exchange for exclusive access. One such scheme, documented by the Connecticut Attorney General, involved membership in an anticompetitive, exclusive "club" of healthcare industry vendors and hospital chief executives: the Healthcare Research and Development Institute ("HRDI").

272. BD and other vendors paid \$40,000 for membership privileges in HRDI, enabling BD direct access to CEO's from the nation's premier hospitals and healthcare institutions. BD and others paid the CEO members an average of \$20,000 to \$25,000 annually to attend conferences with luxury accommodations for them and their spouses and to meet with vendors. Some of the CEO's were paid upwards of \$40,000 to \$50,000. HRDI's "Rule of 2" boosted leverage for the participating vendors such as BD by allowing only two vendors in a particular line of commerce access to these CEO's.

273. In announcing a settlement in January 2007, the Connecticut Attorney General stated as follows:<sup>52</sup>

HRDI claimed to offer health care consulting services to industry players. In reality, it was an exclusive network that shut out potential competitors in various health care markets — everything from pharmaceuticals, syringes, medical devices and financial and consulting services.

These practices threatened to inflate health care costs to patients and taxpayers — stifling competition in almost every health care supply and services market. . . .

. . . vendors intentionally exploited the opportunities provided by HRDI, resulting in an uneven playing field and less competitive selling environment. Vendors gained direct access to hospital CEOs who potentially wielded influence over service and supply purchasing decisions at their respective hospitals.

274. BD was a paying member of HRDI since July 2004 through at least January 2007 and illegally used its membership to exclude Retractable from safety needle products markets.

275. Upon information and belief, BD continues the same or similar practices under the guise of membership in other organizations, including but not limited to a HRDI spin-off, the National Center for Healthcare Leadership.

---

<sup>52</sup> See <http://www.ct.gov/ag/cwp/view.asp?Q=331254&A=2788>

### **The Cumulative Effect of BD's Conduct Impairs or Destroys Competition**

276. All of the above acts when considered cumulatively and in various combinations have foreclosed the relevant markets from equally efficient competitors such as Retractable. The most efficient means of distribution, large volume contracts with acute care facilities, has been essentially completely blocked by these activities.

277. BD has combined the exclusionary effects of offering bundled rebates that require purchase of a set of products in order to avoid penalty pricing with rebates and pricing tied to market share requirements. The combined effect of both practices is more exclusionary than either practice considered separately.

278. BD also combined these contracting practices with the offer of its infringing Integra syringes, compounding their effects with the tort of patent infringement that essentially allowed BD to say to customers: "We have a retractable syringe – no need to look at the VanishPoint®." This essentially allowed BD to use Retractable's own technology to make its market share discounting, rebates and bundling even more compelling and exclusionary.

279. BD also aimed an intentionally false advertising campaign at acute care facilities that were rushing to comply with the requirements of the Needlestick Prevention Act and new OSHA requirements. BD created new lines of products touted as "safe" and "safety" without any evidence of the truth of those claims and simultaneously disparaged and lied about Retractable's VanishPoint® syringes, overstating their dead space and alleging that their use was more painful. These tactics were used in the market in concert with the exclusionary contracting rebating and bundling to insure that access to large orders from hospitals for newly requires safety syringe products would be blocked to smaller innovative entrants such as Retractable.

280. Finally, the realization that its Integra retractable syringe products were not acceptable in performance had no effect on BD's determination to use those products to maintain market share. From 2004 until 2009 BD kept the 1 cc Integra in the market knowing it was never made within product specifications and was too hard to activate. BD ignored those facts in order to continue to use this defective product as part of its bundling and discounting practices necessary to lock Retractable out of the market. In similar manner, BD ignored the problems of hub leakage, premature plunger collapse and excessive activation force of its 3 cc Integra, continually shelving calls for re-design and failing to properly handle product deficiency reports of its own employees. The 3 cc Integra, remains on sale today so that BD can continue to offer it to an unsuspecting public through its exclusionary contracting.

281. These exclusionary acts were and are most effective in the acute care market which is by far the most efficient means of distribution of safety syringes and safety IV catheters. Substantial foreclosure from the acute care market meant that Retractable's innovation had a smaller payoff than it should have and barred Retractable from sources of capital needed to expand and produce new products as fast as it otherwise would have.

282. BD's exclusionary conduct regarding safety syringes also delayed and deterred entry by Retractable into the related market for syringe bodies. By denying volume sales to Retractable in safety syringes, BD has protected against entry into the market for conventional syringe bodies by Retractable's superior Patient Safe syringe. Had Retractable been able to obtain a foothold in the safety syringe market with its VanishPoint<sup>®</sup> syringes it would have had the scale, expertise, and brand reputation to undertake a successful launch of the Patient Safe.

283. BD's conduct was intended to have and has permanent anticompetitive effects because by excluding Retractable from the market BD was not just delaying the erosion of its

dominance in conventional syringes, it was buying time to shift that dominance over to the growing future market for safety syringes that may well eventually completely obsolete the conventional syringe products.

284. In short, the more protected BD is the higher it can maintain prices and the higher the GPO's fees will be since those fees are a percentage of revenues collected by BD. This explains why the GPO's continue to drive their members to sole source contracts and why BD has engaged in patent infringement, false advertising, market tainting with defective products and other illegal conduct to expand and maintain its monopolies.

285. Thus, the keystone of the almost total foreclosure of Retractable from large volume acute care distribution channels from 2004 to present has shifted from patently exclusionary sole source contracts with the GPO's (prevalent at the time Retractable brought its first case in 1998) to a different but no less destructive scheme. BD, under the GPO guise of lowering costs through standardization, has systematically maintained its market power and therefore the ability to set prices through a web of contracts with large customers and customer groups. The ability to sell those contracts has been enhanced by a false advertising campaign, patent infringement, tainting the market for retractable syringes (where BD cannot compete because of lack of technology) as well as bundling and rebating schemes that cannot be matched by innovative entrants such as Retractable.

286. BD's conduct alleged in this Second Amended Complaint affects interstate trade and commerce. BD's annual revenues are measured in billions of dollars, and BD's products are manufactured and sold throughout the United States, including in Texas. BD's conduct was intended to maintain and extend its market power in the nationwide markets for conventional and safety syringes and needles and safety IV catheters.

### **COUNT 1: VIOLATIONS OF THE SHERMAN AND CLAYTON ACTS**

287. All paragraphs of this Second Amended Complaint are incorporated herein by reference as if fully set forth at length.

288. The relevant geographic market is the United States. The relevant product markets are hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters. BD has monopoly and/or market power in the relevant markets for hypodermic syringes and safety syringes and needles.

289. BD has *not* maintained its monopoly and/or market power in the relevant markets as a result of superior product, business acumen, or historical accident. BD has specifically intended, and continues to intend, through its exclusionary conduct, to willfully maintain its monopoly and/or market power, control prices, exclude competitors, harm consumers, and destroy competition in the relevant markets. Through the activities alleged above, among others, BD has gained, maintained, extended, and attempted to gain monopoly power in violation of Section 2 of the Sherman Act.

290. BD has no legitimate business justification for its exclusionary, anticompetitive conduct.

291. As a direct and proximate result of BD's unlawful actions, Retractable has suffered injury to its business and property. If BD's illegal conduct is not enjoined, Retractable will continue to suffer irreparable harm, and the relevant markets will remain distorted and substantially foreclosed, to the detriment of consumers in the market. Advances in safety needle devices technology that could prevent needlestick injuries and thereby prevent disease and save lives will continue to be excluded from the market because BD exercises monopoly and/or market power to exclude competitors and maintain monopoly prices.

292. BD's taking of Retractable's technology, resulting in the tort of patent infringement, constitutes an illegal act that substantially lessens competition and tends to maintain BD's dominance over the market for safety needle products. BD's patent infringement used for the purpose of maintaining its monopoly violates Section 2 of the Sherman Act.

293. BD's knowing introduction and maintenance in the market of retractable syringe devices which had design flaws so serious that they could and did cause injury and which were never manufactured to specification tainted the entire market for retractable syringe products, causing customers to choose BD's shielded syringe products which do not offer total safety but which are profitable for BD. BD's continued sale into the market of retractable syringe products that performed poorly and in some case were dangerous was done for the purpose of maintaining its monopoly and constitutes a violation of Section 2 of the Sherman Act.

294. BD's false advertising of its syringe products as "safe," "safety," "safety-engineered," and various other similar descriptions in commercial advertising and promotion to describe the nature, characteristics, and qualities of the Safety-Lok, SafetyGlide, and Eclipse syringes constitute illegal acts that substantially lessen competition and tend to maintain BD's monopoly over the markets for safety needle products. Such advertising is clearly false. There is no impartial proof that BD's shielded products are safe, effectively eliminate or reduce needlesticks to the lowest feasible extent, or are significantly more safe than conventional syringes. The representations of safety are likely to induce reliance in light of BD's market dominance and more than hundred year history in syringes and are clearly material to purchasers, attempting to protect their work force and comply with the Needlestick Prevention Act that requires consideration of the safest technology available. The persons who are the targets of these advertisements are unsophisticated in the science of safety engineering and have no reason

not to believe the claims. The claims have been continuing since at least July of 2004 up through the present. BD's market power and size virtually guarantee that rivals such as Retractable cannot cure or correct these false statements. BD's false advertising in order to maintain its monopoly position is a violation of Section 2 of the Sherman Act.

295. BD also falsely advertised that Plaintiffs' VanishPoint<sup>®</sup> syringes had three times more dead space than they did, disparaged VanishPoint<sup>®</sup> syringes as causing splatter and injury and engaged in other acts of false advertising and unfair competition detailed above, all done for the purpose of maintaining its monopoly and constitutes a violation of Section 2 of the Sherman Act.

296. Further, BD has made sales of hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters., and granted discounts and rebates on those sales based on the condition, agreement, or understanding that BD's buyer will not purchase Retractable's products.

297. BD's exclusive dealing violates Section 3 of the Clayton Act because it has foreclosed Retractable from substantial portions of the markets for hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters and because it substantially lessens competition in those markets and maintains BD's monopoly and/or market power over those markets.

298. BD's rebating practices also violate Section 2 of the Sherman Act and Section 3 of the Clayton Act because they exclude Retractable and other BD competitors from substantial portions of the markets for hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters and because such practices substantially lessen competition in those markets and tend to maintain BD's monopoly over those markets.

299. BD's bundling practices also violate Section 2 of the Sherman Act and Section 3 of the Clayton Act because they exclude Retractable and other BD competitors from substantial portions of the markets for hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters and because such practices substantially lessen competition in those markets and maintains BD's monopoly over those markets.

300. BD's various schemes for making indirect payments to hospital purchasing executives, chief executive officers, and others within the healthcare industry have excluded Retractable and other BD competitors from the hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters markets. These anticompetitive practices, which allow BD to have direct access to hospital executives who wield influence over purchasing decisions, have inflated healthcare costs to patients, stifled competition, created an uneven playing field for BD's competitors, and tended to maintain BD's monopoly in these markets violating Section 2 of the Sherman Act.

301. All of the above types of conduct, when viewed as a whole constitute a pattern of repeated, varied, exclusionary practices that has worked violence on the competitive process in the important market for syringes, and in particular the market for safety syringes, as well as the market for safety catheters, threatening to completely block any smaller rival from entering the market with innovative products. The course of conduct as a whole violates Section 2 of the Sherman Act.

302. With intent to unreasonably restrain competition, BD entered into contracts, combinations, and conspiracies in restraint of trade with one or more entities, which froze competitors out of markets, harmed competition, and foreclosed competition in a substantial share of the lines of commerce affected. These acts violate Section 1 of the Sherman Act.

303. From and after July 2, 2004, Retractable has been directly and proximately damaged by losses of sales and profits resulting from BD's exclusive dealing, rebating, bundling arrangements, patent infringement, market tainting, false advertising, indirect payments to decision makers at hospitals, and other monopolistic and exclusionary practices. Retractable seeks damages, treble damages, reasonable attorneys' fees, costs of court, and all other relief available to it under the antitrust laws. Retractable will be irreparably harmed if BD's exclusive dealing, rebating and bundling arrangements, market tainting and false advertising are not enjoined.

304. Alternatively, BD has specifically intended, and continues to intend, through its exclusionary conduct, to control prices, exclude competitors, and destroy competition in the relevant markets for hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters. Through the activities alleged in the paragraphs above, among others, BD has attempted to gain monopoly power in the markets for hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters. BD's predatory and anticompetitive conduct presents a dangerous probability that BD will succeed in monopolizing the hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters markets because BD already has significant market share in those markets, which contain high barriers to entry in the form of capital costs, intellectual property requirements and costs, and other burdens. As a direct and proximate result of BD's anticompetitive conduct alleged herein, Retractable has been injured in its business and property and suffered substantial lost profits, and will continue to suffer irreparable harm if BD is not enjoined from continuing its illegal course of conduct.

305. Still further, BD has specifically intended, and continues to intend, through its alleged conduct, to control prices, exclude competitors, and destroy competition in the relevant

markets for hypodermic syringes, safety syringes and needles, IV catheters and safety IV catheters by leveraging its monopoly power in the broader syringe market. Thus, even if BD has through some natural or legal advantage (which is specifically denied) gained monopoly power in the market for conventional syringes, it has illegally exploited that position in order to expand its empire to the market for safety syringes and needles, IV catheters and safety IV catheters.

### **COUNT 2: TEXAS ANTITRUST ACT**

306. All paragraphs of this Second Amended Complaint are incorporated herein by reference as if fully set forth at length.

307. BD's conduct outlined in the federal antitrust violations detailed above also violates the Texas Free Enterprise and Antitrust Act of 1983, Tex. Bus. & Com. Code Ann. § 15.01 *et seq.* (Vernon 2003). Retractable seeks an injunction, an award of damages, treble damages, recovery of its reasonable attorneys' fees, and all other relief available under said Texas Act. If BD's illegal conduct is not enjoined, Retractable will continue to be irreparably damaged and Texas markets for safety needle devices will be substantially foreclosed to competition.

### **COUNT 3: FALSE ADVERTISING IN VIOLATION OF SECTION 43(A) OF THE LANHAM ACT**

308. All paragraphs of this Second Amended Complaint are incorporated herein by reference as if fully set forth at length.

309. BD has used, in its commercial advertising and promotion in interstate commerce, words, terms, names, and combinations thereof, that constitute false and misleading descriptions and misrepresentations of fact concerning the nature, characteristics, and qualities of its Safety-Lok, SafetyGlide, Eclipse and Integra products and of Retractable's VanishPoint® products.

This false and misleading advertising and promotion by BD has occurred after July 2, 2004, continues to the present, is material to consumers' purchasing decisions, has deceived and had a tendency to mislead consumers, has profited BD, and has harmed Retractable.

310. BD's false and misleading advertising and promotion injures competition, Plaintiffs, and the American public, especially healthcare workers. By promoting the Safety-Lok, SafetyGlide, and Eclipse as "safe" when in fact they are not, BD implies to healthcare workers and healthcare employers not only that the products provide protection from needlestick injuries, but also, and just as damaging, that purchase and use of such products will place the healthcare entity in "compliance" with the provisions of the Needlestick Prevention Act. Thus, false advertising allows BD to sell its high-profit-margin, unsafe "safety" products and needles to circumvent the intent of the Needlestick Prevention Act and thereby block adequate consideration of Retractable's clearly safer technology.

311. The foregoing descriptions, representations, and statements are illustrative, not exhaustive. BD's false and misleading descriptions, representations, statements, advertising, and promotions, described herein or otherwise, have been knowing, intentional and willful, made in bad faith with malice towards competitors and intent to defraud consumers, have deceived or had the tendency to deceive a substantial portion of the intended audience in a material manner, and have influenced or had the likelihood to influence purchasing decisions, especially given their frequency and prominence in BD's marketing campaign.

312. Moreover, BD's wrongful acts have caused, and will continue to cause, Retractable to incur substantial damages, including, but not limited to, declining sales, loss of goodwill, lost profits, and loss of market share. Retractable therefore seeks recovery from BD of all amounts it is entitled to under 15 U.S.C. § 1117(a), including, without limitation: (1) BD's

profits related to its false and misleading descriptions, representations, statements, advertisements, and promotions; (2) all damages sustained by Retractable; (3) the costs of this action; (4) treble damages, (5) reasonable attorneys' fees; and (6) an additional amount that the Court considers just.

313. Retractable pleads for prospective injunctive relief to enjoin BD's ongoing false and misleading descriptions, representations, statements, advertisements, and promotions under 15 U.S.C. § 1116(a).

314. BD has acted with unclean hands, and Retractable's claims under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), further the public interest.

#### **COUNT 4. PRODUCT DISPARAGEMENT**

315. All paragraphs of this Second Amended Complaint are incorporated herein by reference as if fully set forth at length.

316. Defendant BD disparages the VanishPoint<sup>®</sup> syringe by maintaining its inferior quality retractable Integra on the market, thereby tainting the consumer market for the entire product category of retractable safety needle devices. BD maintains the Integra on the market even though BD knows that the Integra was poorly designed and is of inferior quality. Customers having poor experiences with Integra's inferior quality and design are likely to turn their backs on the entire product category of retractable safety needle devices, including the VanishPoint<sup>®</sup>. BD enjoys higher profit margins on its other devices, and a tainted consumer market for retractable safety needles does not adversely affect BD nearly as much as it does Retractable. By disparaging the entire product category of retractable safety needle devices, BD can benefit from decreased competition from Retractable with its retractable VanishPoint<sup>®</sup> syringe.

317. Defendant BD's disparaging of the VanishPoint<sup>®</sup> syringe by maintaining its inferior quality Integra on the market was done and continues to be done with malice. BD maintains the Integra on the market even though it knows that it is of inferior design and quality. It does this to taint the entire consumer market for retractable safety needle devices, including the VanishPoint<sup>®</sup>. This behavior is undertaken with the intent to drive Retractable out of the broader safety needle market in which BD enjoys considerable market power.

318. BD's published false and disparaging information about Retractable's VanishPoint<sup>®</sup> syringe. BD sales representatives falsely attacked the VanishPoint<sup>®</sup> syringe's retraction feature by claiming or implying that the dead space of the VanishPoint<sup>®</sup> is greater than it is and that the retraction of the safety feature is harmful to the patient. Moreover, BD advertises the SafetyGlide and Eclipse as having no negative impact on the patient because the safety feature activates after the needle is withdrawn from the patient. These statements falsely imply that retractable safety needle products like the VanishPoint<sup>®</sup> syringe do have a negative impact on patients, thereby further disparaging the VanishPoint<sup>®</sup> syringe.

319. Defendant BD's false and disparaging information was published about the VanishPoint<sup>®</sup> syringe with malice. Even though BD understands that eliminating the critical exposure period (after injection or blood-drawing and before disposal into a sharps container) increases safety, it nevertheless continues this false attack on VanishPoint<sup>®</sup> and retraction technology.

320. Defendant BD was not in anyway privileged to disparage the VanishPoint<sup>®</sup> syringe in the ways that it has and continues to do.

321. As a result of BD's disparagement, Plaintiff Retractable has suffered special damages in the form of harm to its economic interests in the VanishPoint<sup>®</sup> syringe.

**COUNT 5: TORTIOUS INTERFERENCE WITH  
PROSPECTIVE CONTRACT OR BUSINESS RELATIONS**

322. All paragraphs of this Second Amended Complaint are incorporated herein by reference as if fully set forth at length.

323. After July 2, 2004 Plaintiff Retractable had opportunities to enter into prospective contractual or business relations with hospitals and healthcare centers. After state and federal laws were enacted requiring hospitals and healthcare centers to use safety needles that would prevent needlestick injuries, the demand for safety needle products increased. After 2004, Retractable sent out teams of salespersons to healthcare centers around the country where they offered Retractable's safety VanishPoint<sup>®</sup> syringes for sale. Realizing the superior safety features and ease of use of the VanishPoint<sup>®</sup> syringe, practitioners and other healthcare employees conveyed great interest in placing orders with Retractable's sales teams.

324. A reasonable probability existed that Retractable would have obtained these orders thereby establishing contractual or business relations with these hospitals and healthcare centers.

325. BD interfered with Retractable's prospective contractual or business relations with hospitals and healthcare centers with its independently tortious conduct of product disparagement and false advertising. BD sales representatives falsely attacked the VanishPoint<sup>®</sup> syringe's retraction feature by claiming or implying that the retraction of the safety feature is harmful to the patient. BD also falsely represented the amount of dead space in Retractable's products. BD also made false representations regarding its own product as discussed in the above paragraphs to try and prevent potential customers from purchasing VanishPoint<sup>®</sup> products instead of its own products. The statements were made by BD with the intent to prevent

execution of the prospective orders or contracts. They were false and disparaging and were therefore independently tortious in nature.

326. Defendant BD interfered with Retractable's prospective contractual or business relations with hospitals and healthcare centers with its independently tortious conduct of patent infringement. BD has directly, indirectly, and/or contributorily infringed the Retractable's patents by manufacturing, using, selling, and offering for sale retractable syringes covered by Retractable's patents. Such manufacture, use, and sale was undertaken by BD with the intent to prevent execution of the prospective orders or contracts.

327. These actions constituted patent infringement and were therefore independently tortious in nature. Defendant BD also interfered with Retractable's prospective contractual or business relations with hospitals and healthcare centers with illegal acts in violation of the Lanham Act. BD has misleadingly or falsely advertised its Safety-Lok, SafetyGlide, and Eclipse syringes with terms such as "safe," "safety," or "safety-engineered." BD's false representations have influenced or had the likelihood of influencing the purchasing decisions of a substantial portion of the intended audience in a material manner. The defendant took these actions with the intent to prevent execution of the prospective orders or contracts. These actions constituted violations of the Lanham Act and were therefore wrongful and in violation of statutory law.

328. Defendant BD also interfered with Retractable's prospective contractual or business relations with hospitals and healthcare centers with illegal acts in violation of the Sherman and Clayton Acts. BD has maintained its monopoly and/or market power in the Safety Needle Device market for acute care and alternate care centers with its bundling practices, price control, discounts and rebates conditioned on exclusive or near-exclusive purchasing from BD, exclusion of Retractable from trade shows, and schemes for indirect payments to hospital

purchasing executives and chief executive officers. The foregoing behaviors are illustrative and not exhaustive. The defendant took these actions with the intent to prevent execution of the prospective orders or contracts. These actions constituted violations of the Sherman and Clayton Acts and were therefore wrongful and in violation of statutory law.

329. Defendant BD also interfered with Retractable's prospective contractual or business relations with hospitals and healthcare centers with illegal acts in violation of the Texas Antitrust Act. BD has maintained its monopoly and/or market power in the safety needle products market for acute care and alternate care centers with its bundling practices, price control, discounts and rebates conditioned on exclusive or near-exclusive purchasing from BD, exclusion of Retractable from trade shows, and schemes for indirect payments to hospital purchasing executives and chief executive officers. The foregoing behaviors are illustrative and not exhaustive. The defendant took these actions with the intent to prevent execution of the prospective orders or contracts. These actions constituted violations of the Texas Antitrust Act and were therefore wrongful and in violation of statutory law.

330. Plaintiff Retractable has lost the opportunity to enter into prospective contract or business relations as a result of this interference through independently tortious and wrongful conduct by BD.

331. Defendant BD's interference with Retractable's prospective contract or business relations with hospitals and healthcare centers has caused Retractable substantial damages, including, but not limited to, declining sales, loss of goodwill, lost profits, and loss of market share.

332. Further, Plaintiff Retractable will show that Defendant BD acted intentionally and with malice for the sole purpose of excluding Retractable from the safety needle products market.

#### **COUNT 6: UNFAIR COMPETITION**

333. All paragraphs of this Second Amended Complaint are incorporated herein by reference as if fully set forth at length.

334. BD's alleged tortious conduct constitutes unfair competition in violation of the common law. BD and Retractable are competitors. BD has unfairly competed with and sought to destroy Retractable's business.

335. Plaintiff Retractable has suffered damage as a result of such conduct.

#### **INJUNCTIVE RELIEF**

336. All paragraphs of this Second Amended Complaint are incorporated herein by reference as if fully set forth at length.

337. Retractable is entitled to a permanent injunction preventing BD from continuing to advertise its Safety-Lok, SafetyGlide, and Eclipse syringes using false and misleading descriptions and representations of fact, such as "safe," "safety," and "safety-engineered."

338. Retractable is entitled to a permanent injunction preventing BD from (a) continuing to publish any of the advertisements described above; (b) misrepresenting the dead space, dose accuracy, and medication savings associated with Retractable's VanishPoint® syringes and with BD's Safety-Lok, SafetyGlide, Eclipse, and Integra syringes; (c) advertising about dead space, dose accuracy, and medication savings without describing the negative impact on those qualities of non-integral needles and needle changing and stating which BD syringes have non-integral or changeable needles; (d) advertising about the dead space, dose accuracy,

and medication savings of the Integra 3 mL syringe without prominently disclosing its problems with leakage, premature plunger rod collapse, and needle pop-off and describing their negative impact on dead space, dose accuracy, and medication savings; (e) except in the case of corrective advertising that may be ordered by this Court, referring in any future advertising to any of the analyses, studies, tests or other information found to be false or to not actually support BD's establishment claims (i.e., "Data on file"); and (f) representing that BD has data on file to support any claims pertaining to syringes when such data is more than two years old.

339. Retractable is entitled to a permanent injunction preventing BD from claiming or implying that activating retraction of the VanishPoint® needle while it is still in the patient harms or has a "negative impact to" the patient and from claiming or implying that activation after the needle is withdrawn is an advantage of BD products.

340. Retractable is entitled to a permanent injunction preventing BD from claiming that its Eclipse, SafetyGlide, and Integra products feature single-handed activation.

341. Retractable is entitled to a permanent injunction preventing BD from claiming or implying that its products feature "The World's Sharpest Needle" or that BD needles are not dulled as easily and are more comfortable than other needles, including Retractable's needles.

342. Retractable is entitled to a permanent injunction preventing BD from using the false and misleading phrase "Why can't it be zero?" in its advertising or promotions or otherwise stating or implying that BD's Safety-Lok, Eclipse, SafetyGlide, or Integra products reduce needlestick injuries to the maximum extent possible.

343. Retractable is entitled to a permanent injunction preventing BD from continuing any advertising or promotion proven false or misleading, material and deceptive.

344. Retractable is entitled to injunctive relief in the form of an order compelling BD to contact in writing each of its customers, distributors, targeted accounts, U.S. and state governmental entities, and any other businesses that have or may have received any of the false or misleading advertising, specifically identifying the false or misleading claims, stating why they are false and misleading, enclosing a copy of the Court's order forbidding dissemination of such false and misleading advertising, and requesting that materials containing such claims be removed from their facilities, files, and web sites and that further dissemination cease.

345. Retractable is entitled to a permanent injunction enjoining BD from continuing actively to exclude Retractable from the markets described herein, and requiring BD to take corrective action to remedy distortions in said markets caused by BD's continuing violations of the federal and Texas antitrust laws.

346. Injunctive relief would greatly serve the consumers and the public interest because the consuming public has an interest in accurate information about healthcare products; the public has an interest in competitive markets; the public has an interest in preventing injuries to healthcare workers on whom it depends for medical services; and Retractable's products could prevent more needlestick injuries, which serves the public interest by saving substantial costs for medical testing and preventing more instances of disease and death.

347. BD's violations of federal and Texas law are continuing, and BD has demonstrated that it will continue in all of the conduct described herein unless enjoined. Retractable is threatened with irreparable harm from these continuing and future violations.

### **PRAYER FOR RELIEF**

WHEREFORE, PREMISES CONSIDERED, Plaintiff Retractable Technologies, Inc. and Plaintiff Thomas J. Shaw pray that Defendant Becton Dickinson and Company will be cited to appear and answer herein and for Judgment of this Honorable Court as follows:

(a) Enjoining BD from continuing the anticompetitive conduct alleged in this Second Amended Complaint;

(b) Ordering BD to take corrective steps to end the foreclosure of the relevant market and create a competitive market for Safety needle devices and to remedy the market distortions created by its past and continuing violations of the United States antitrust laws;

(c) Ordering BD to contact in a writing, to each of its customers, distributors, targeted accounts, U.S. and state governmental entities, and any other businesses that have or may have received any of the false or misleading advertising, specifically identifying the false or misleading claims, stating why they are false and misleading, and enclosing a copy of the Court's order forbidding dissemination of such false and misleading advertising;

(d) Awarding Retractable treble damages resulting from BD's antitrust violations;

(e) Awarding Retractable (i) BD's profits, (ii) Retractable's damages, and (iii) costs of the action, pursuant to 15 U.S.C. § 1117(a) as well as for the common law unfair competition;

(f) Awarding Retractable (i) Retractable's damages, and (ii) costs of the action in connection with the tortious interference with prospective contract or business relations and product disparagement claims;

(g) Awarding Retractable all reasonable attorneys' fees allowed by statute, expert fees, costs, pre-judgment interest, and post-judgment interest; and

(h) Granting all such other relief, at law and in equity, to which Plaintiffs are entitled.

**JURY DEMAND**

348. Plaintiffs' demand a trial by jury as is their right under the Seventh Amendment to the Constitution of the United States or as given by statute. FED. R. CIV. P. 38.

Dated: July 23, 2010

Respectfully submitted,

/s/ Roy W. Hardin

Roy W. Hardin

Texas Bar No. 08968300

George E. Bowles

Texas Bar No. 02743300

Stephen D. Wilson

Texas Bar No. 24003187

Paul Schuster

Texas Bar No. 00784931

LOCKE LORD BISSELL & LIDDELL LLP

2200 Ross Avenue, Suite 2200

Dallas, Texas 75201-6776

Telephone: (214) 740-8000

Facsimile: (214) 740-8800

E-mail: [rhardin@lockelord.com](mailto:rhardin@lockelord.com)

Otis Carroll

State Bar No. 03895700

Deborah Race

State Bar No. 16448700

IRELAND, CARROLL & KELLEY, PC

6101 S. Broadway, Suite 500

Tyler, Texas 75703

Tel. (903) 561-1600

Fax (903) 581-1071

Email: [Fedserv@icklawn.com](mailto:Fedserv@icklawn.com)

ATTORNEYS FOR PLAINTIFFS,  
RETRACTABLE TECHNOLOGIES, INC. and  
THOMAS J. SHAW

Of counsel:

G. William Lavender  
Lavender Law  
210 N. State Line Ave., Suite 503  
Texarkana, Arkansas 71854  
Telephone: (870) 773-3187  
Facsimile: (870) 773-3181  
E-mail: blav@lavenderlaw.com

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3).

/s/ Roy W. Hardin  
Attorney for Plaintiffs, Retractable Technologies, Inc.  
and Thomas J. Shaw